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# RESEARCH ON HUMAN SKIN LASER DAMAGE THRESHOLDS

R. James Rockwell, Jr., et al

Cincinnati University

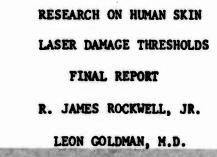
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June 1974

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# DEPARTMENT OF DERMATOLOGY AND LASER LABORATORIES MEDICAL CENTER, UNIVERSITY OF CINCINNATI CINCINNATI, OHIO

RESEARCH ON HUMAN SKIN

LASER DAMAGE THRESHOLDS

FINAL REPORT

R. JAMES ROCKWELL, JR.

LEON GOLDMAN, M.D.

June, 1974

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Results are presented of experimental studies to determine the threshold level for minimal reaction produced on human skin by six (6) different laser systems. A description is given of the equipment used, and the method of data recording.

Data from patients tested yielded a fifty percent probability for producing a minimal reaction on the skin at doses (MRD<sub>50</sub>) ranging from 11 to 20 J/cm<sup>2</sup> for Caucasian skin and 2.2 to 6.9 J/cm<sup>2</sup> for Negro skin, following a ruby laser exposure of 2.5 msec; (continued)

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20. Abstract (cont.)

a MRD<sub>50</sub> ranging from 0.25 to 0.34 J/cm<sup>2</sup> for Caucasian skin and 0.25 to 0.34 J/cm<sup>2</sup> for Negro skin following a Q-switched ruby laser exposure of 75 nsec; a MRD<sub>50</sub> ranging from 4.0 to 8.2 J/cm<sup>2</sup> for Caucasian skin and 4.5 to 6.0 J/cm<sup>2</sup> for Negro skin following an argon laser exposure of 1.0 sec; a MRD<sub>50</sub> of 2.8 J/cm<sup>2</sup> for both Caucasian and Negro skin following a carbon dioxide laser exposure of 1.0 sec; a MRD<sub>50</sub> ranging from 4.2 to 5.7 J/cm<sup>2</sup> for Caucasian skin and 2.5 to 3.0 J/cm<sup>2</sup> for Negro skin following a Q-switched neodymium-glass laser exposure of 75 nsec; a MRD<sub>50</sub> of 48 to 78 J/cm<sup>2</sup> for Caucasian skin and a MRD<sub>50</sub> ranging from 46 to 60 J/cm<sup>2</sup> for Negro skin following neodymium-YAG (CW) laser exposure of 1.0 sec. Analysis of all MRD<sub>50</sub> levels was done at one-hour post-exposure.

10

The research program whose results are presented in this report was initiated by the United States Air Force School of Aerospace Medicine, Aerospace Medical Division, Brooks Air Force Base, Texas, under Contract F41609-72-C-0007. The technical monitors have been Major Irving Dunsky and Captain Peter Laudieri.

The research reported covers a period from November 15, 1971 to December 15, 1973. The studies represent a joint effort at the University of Cincinnati Medical Center by the Department of Dermatology and the Laser Laboratory. Dr. Leon Goldman, M.D. served as project leader from the Department of Dermatology and Mr. R. James Rockwell, Jr. served as project leader from the Laser Laboratory

Publication of this report does not constitute Air Force approval of the report's findings or conclusions. It is published only for the exchange of stimulation of ideas.

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#### I INTRODUCTION

This report gives the results of a two-year study to determine the lowest radiant exposure levels at which the first observable reactions occur on human skin exposed to electromagnetic radiations emitted by normal mode and Q-switched ruby, Q-switched neodymium-glass, carbon dioxide, argon and neodymium-YAG laser devices. The principal goal of the study was to establish the 50 percent probability dose for such minimal reactions observed one-hour post-exposure. Such minimal radiant exposure levels are defined, for the purpose of this report, as the fifty percent probability dose for minimal reactions, and are designated as MRD<sub>50</sub> (Minimal Reaction Dose, 50% probability).

Since the development of the laser in the early 1960's, considerable effort has been made to determine the various biologic effects of the intense coherent radiation emitted by these devices. Most of this effort has been expended to determine the ocular effects. Only a few limited studies have been made to establish, in a quantitative way, the levels producing reactions in skin. Early studies by Goldman and Rockwell (1)\* established preliminary values for MRD levels of human Caucasian skin for the normal mode and Q-switched ruby laser, the argon laser and the carbon dioxide laser. Kuhn (2), et al determined the reactive dose of pig skin (both pigmented and non-pigmented) following normal mode ruby laser exposures. Brownell (3), et al established the minimal erythemal dose (MED) of pig skin following carbon dioxide laser exposure.

<sup>\*</sup>References listed at the end of the report.

Parr (4) has reviewed this early work and discussed its influence upon the levels chosen for various laser safety standards. It is of note that Parr indicated in his review the available skin exposure data "has been meager and has dealt mostly with catastrophic types of damage."

Williams (5), et al studied the effects on human skin of Q-switched ruby and neodymium, argon and carbon dioxide laser radiation. These experiments, however, yielded only minimal quantitative data which was not useful for MRD evaluations.

Goldman and Rockwell (6) have previously discussed the influence of skin pigmentation on the absorption efficiency of laser radiation. As they reviewed, one technique to determine the relative absorption of radiant energy in human tissues is the use of reflectance spectroscopy. This method, which has been previously documented in detail by Kuppenheim (7) using standard non-coherent sources and reflectance measurement equipment, is based upon the theory that all of the radiant energy incident upon the skin which is not directly absorbed - or internally scattered and absorbed - will be backscattered and can be detected by a reflectance spectrophotometer. Hence, a measure of the backscattered radiation can yield a first order quantitation of the total absorbed radiation.

This present study attempts to quantitate the radiant exposure levels at which minimal reactions occur in human skin at one-hour following exposure to laser radiation. In an effort to quantitate the influence of skin pigmentation, reflectance spectrophotometry was done prior to exposure on each subject in the general area of the arm of the subject which was irradiated.

Also, to provide the extremes of pigmentation, both Negro and Caucasian subjects were chosen for each laser system.

Prior to each exposure session, the radiant exposure of the laser (as measured at the exit of a standard 1.05 cm aperture) was calibrated as a function of a monitor system. In this manner, the exposure levels on the skin could be reproduced from subject to subject during the session.

The skin reaction data was obtained by examining the areas exposed at five minutes, one-hour and at 24 hours. In general, the five-minute reaction at a given radiant exposure level served as a guide in determining whether more exposures should be given at increased radiant exposure levels. In general, a very mild erythematous reaction at five-minutes will probably fade at one-hour. This level would represent the lowest level to be used. A definite well demarcated erythematous reaction on the skin at five-minutes will probably be present at one-hour. This would, therefore, represent the highest level of exposure. There were many exceptions to this approximation which are evident in the data of individual patients.

At one-hour, each area exposed was again examined and photographed.

The number of "reactions" (this could be erythema, papules, blanching, ashen char, etc) were determined at each exposure level. A similar examination was done at 24 hours post-exposure. This data, expressed as a percentage of the reactions observed at each exposure level, was plotted on probability paper and the radiant exposure at the 50 percent probability level was taken as the MRD<sub>50</sub> level.

In some cases, due to a limited number of suitable volunteers, a given subject was exposed to a different laser radiation on the arm not previously treated. In some limited cases, areas of the same arm previously treated were treated a second time with a different laser radiation, but at no time was an area

of a given subject exposed to a second form of laser radiation if there was any observable lesion or effect in that area from a prior laser exposure or trauma of any other nature.

Once the data was compiled, an effort was made to quantitate the  $MRD_{50}$  levels with the magnitude of absorption in the subject at the laser wavelength in question. As a result, data is presented which would allow one to estimate  $MRD_{50}$  levels for subjects of a given absorption level.

The MRD $_{50}$  levels obtained were also compared with existing values for permissible exposure of the skin in the ANSI-Z-136.1 Standard on Safe Use

#### II EXPERIMENTAL PROCEDURES

#### A. The Laser Systems

The following sections will detail the experimental aspects of the quantitation for the six (6) laser systems used in the study.

#### 1. Normal Mode Ruby Laser

#### a. Laser Characteristics

1. Type: Ruby (12"x5/8" solid crystal)

2. Make: Spacerays

3. Model: No. 5000

4. Operation: Pulsed: 2.5 msec nominally

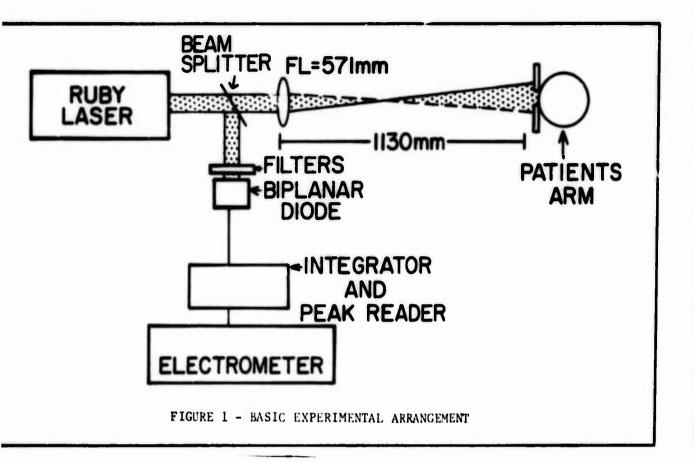
5. Wavelength: 694.3 nm

#### b. Delivery

The beam from a normal-mode pulsed ruby laser was partially focused by a long focal length lens (FL=571 mm) on a 1.05 cm hole in a metal diaphragm placed 1130 mm from the lens. As a result, the size of the large laser beam (2.4 cm) was reduced and the beam passing through the hole has a nearly uniform beam cross-section. In this way, a nearly uniform radiant exposure is presented to the skin surface. The basic arrangement is shown diagramatically in Figure 1.

#### c. Calibration

A beam-splitter arrangement interposed between the laser and the focusing lens allowed for a monitored measure of laser performance.



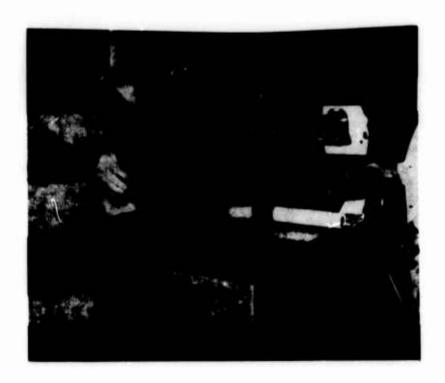


FIGURE 2 - EXPERIMENTAL SETUP FOR NORMAL-MODE RUBY LASER TESTS

The beam-split-beam, after a reduction in intensity by glass absorption filters, was directed onto a FW-114 biplanar photodiode. The output from this device was electronically integrated and fed into a peak detector circuit. The integrated peak was monitored on a Keithley 610 Electrometer Voltmeter and provided a direct voltage measure proportional to the total pulse energy. The readings of this device were then calibrated as a function of the energy passing through the hole in the metal diaphragm as measured by a Hadron-TRG cone calorimeter and Keithley Microvolt meter. The radiant exposure (J/cm²) passing through the diaphragm was then calculated and this data was plotted as a function of the monitor reading. The overall experimental setup is shown in Figure 2.

#### d. Patient Preparation

The patient's arm was then mapped into 25 small sectors such as shown in Figure 3. Five identical doses at each of five different radiant exposures were presented in this matrix. The irradiated areas were examined at five-minutes, one-hour and at 24 hours.

Presence of any visible reaction (erythema, papules, etc.) in the area was recorded as a reaction.



FIGURE 3 - MATRIX MAPPING OF ARM (PRE-LASER-EXPOSURE)

#### 2. Argon Laser

#### a. Laser Characteristics

1. Type: Argon Ion

2. Make: Spacerays

3. Model: No. 5600

4. Operation: CW with 1.0 sec shutter

5. Wavelength: 488-514 nm

#### b. Delivery

The beam from a continuous wave argon laser was directed onto a 1.05 cm hole in a metal diaphragm placed approximately four meters from the exit mirror of the laser. As a result of the large beam divergence (2mrad) the size of the laser beam at this point was larger than the aperture and the beam passing through the hole presented a more nearly uniform beam cross-section. In this way, a nearly uniform irradiance is presented to the skin surface. The basic arrangement is shown in Figure 4.

#### c. Calibration

All exposures were limited to 1.0 seconds by an electronic shutter interposed in the beam. A beam-splitter arrangement interposed between the laser and the aperture allowed for a monitored measure of laser performance. The portion of the beam reflected by the beam-splitter, after a reduction in intensity by glass absorption filters, was directed onto a FW-114 biplanar photo-diode. The exposure was electronically

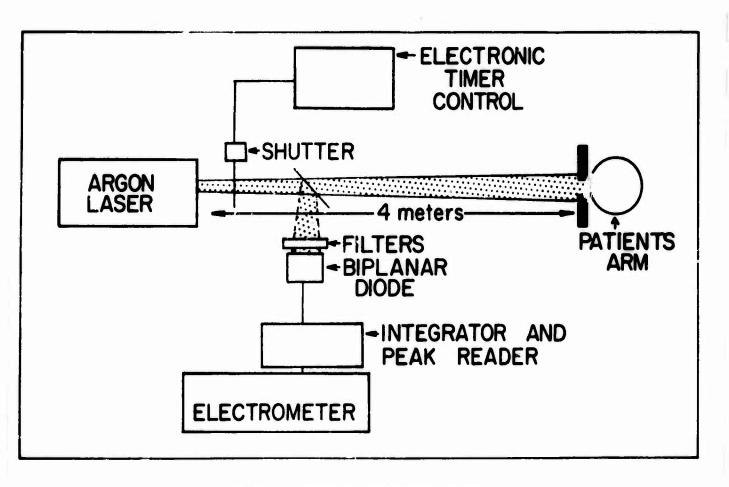


FIGURE 4 - BASIC EXPERIMENTAL SETUP



FIGURE 5 - EXPERIMENTAL SETUP FOR ARGON LASER TESTS

integrated and fed into a peak detector circuit. The integrated peak was monitored on a Keithley 610 Electrometer Voltmeter and provided a direct voltage measure proportional to the total exposure energy. The readings of this device were then calibrated as a function of the energy passing through the hole in a metal diaphragm during each 1.0 sec exposure as measured by a Hadron-TRG cone calorimeter and Keithley microvolt meter. The radiant exposure (J/cm²) passing through the diaphragm was then calculated, and this data was plotted as a function of the monitor reading. The overall experimental setup is shown in Figure 5.

Laser charge levels were then selected which yielded radiant exposures ranging from 0.9 to 10 J/cm² at the

#### 3. Carbon Dioxide Laser

#### a. Laser Characteristics

1. Type: Carbon Dioxide

2. Make: American Optical

3. Operation: CW, with 1.0 sec shutter

4. Wavelength: 10,600 mm

#### b. Delivery

The beam from a carbon dioxide laser was directed onto a 1.05 cm hole in a metal diaphragm placed approximately two meters from the exit mirror of the laser. The beam is directed to this point by reflections from five elbow joints in an articulating arm arrangement. As a result of the large beam size, the laser beam at this point is larger than the aperture. The laser operates at a high order mode distribution and presents a relatively uniform irradiance on the skin surface. The basic arrangement is shown diagramatically in Figure 6.

#### c. Calibration

All exposures were limited to 1.0 seconds by an electronic shutter interposed in the beam. A CRL Thermopile was interposed in the laser beam prior to exposures and allowed for calibration of the laser performance. The stability of the laser performance was sufficient to eliminate the need for continuous power monitor. Exposure energies were obtained by measuring the power passing

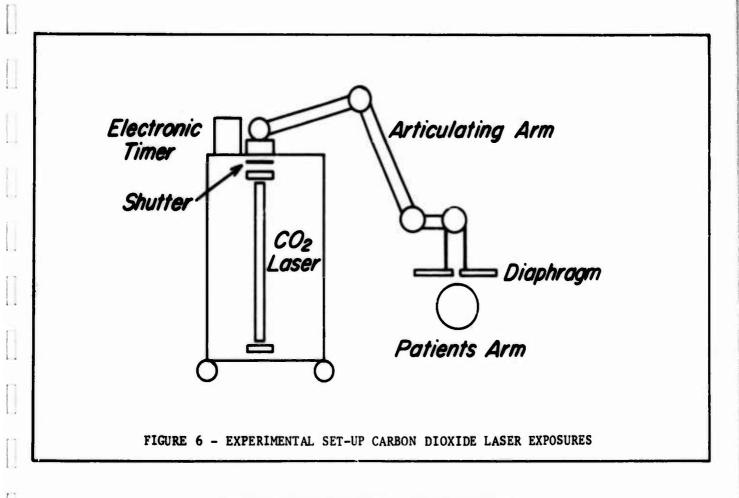




FIGURE 7 - EXPERIMENTAL SETUP FOR CO<sub>2</sub> LASER EXPOSURES

through the aperture and then calculating the energy which would pass for a 1.0 second exposure. The radiant exposure  $(J/cm^2)$  passing through the diaphragm was then calculated.

Laser control settings were then selected which yielded radiant exposures ranging from 0.6 to 2.9  $\rm J/cm^2$  at the diaphragm.

## 4. Neodymium-YAG Laser

#### a. Laser Characteristics

1. Type: Neodymium-YAG solid crystal

2. Make: Holobeam

3. Model: 2500-2 (200 watt CW)

4. Operation: CW with 1.0 sec shutter

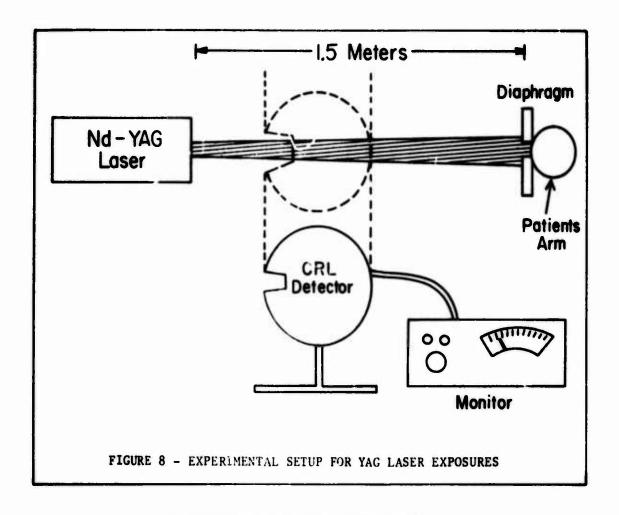
5. Wavelength: 1060 nm

#### b. Delivery

The beam from a continuous wave neodymium-YAG laser was directed onto a 1.05 cm hole in a metal diaphragm placed approximately one meter from the exit mirror of the laser. As a result of the large beam divergence from this laser, the size of the laser beam at this point was larger than the aperture, and the beam passing through the hole presented a nearly uniform beam cross-section. In this way a uniform irradiance is presented to the skin surface. The basic arrangement is shown diagramatically in Figure 8.

#### c. Calibration

All exposures were limited to 1.0 seconds by an electronic shutter interposed in the beam. The system was calibrated by using a CRL Thermopile Detector to measure the total exiting power directly from the laser. The laser performance was sufficiently stable to allow an interposition method to relate the output level at a given set-level of



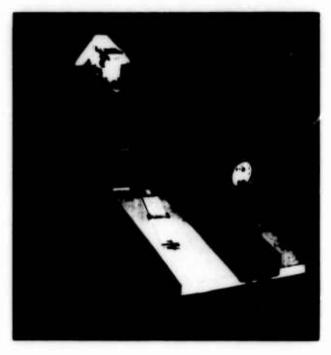


FIGURE 9 - EXPERIMENTAL SETUP FOR YAG LASER EXPOSURES

the power supply.

At a given set-level, the CRL head was interposed into the beam path to give a monitor reading. The shutter was then closed and the thermopile removed. The readings of the thermopile were then correlated to the total radiant energy passing through the hole in the metal diaphragm during each 1.0 second exposure. The energy was measured by a Hadron-TRG cone calorimeter and Keithley Microvolt-meter. The radiant exposure (J/cm<sup>2</sup>) passing through the diaphragm was then calculated and this data was plotted as a function of the CRL Thermopile "monitor" reading. The overall experimental setup is shown in Figure 9.

Laser charge levels were then selected which yielded radiant exposures ranging from 20 to 80  $\mathrm{J/cm}^2$  at the diaphragm.

#### 5. Q-Switched Ruby Laser

#### a. Laser Characteristics

1. Type: Ruby (7"x9/16" solid crystal)

2. Make: Spacerays

3. Model: 1010QDC2 - Oscillator-amplifier

4. Operation: Pockel cell Q-switched laser pulse @ 75 nsec

5. Wavelength: 694.3 nm

#### b. Delivery

The beam from a Q-switched ruby laser was directed onto a 1.05 cm hole in a metal diaphragm placed approximately 1.5 M from the end of the laser rod. As a result, only the central portion of the divergent laser beam passed through the hole with a relatively uniform beam crosssection. In this way, a nearly uniform radiant exposure is presented to the skin surface to be irradiated. For some exposures, glass filters were interposed in the beam to allow for lower radiant exposure levels. The basic arrangement is shown diagramatically in Figure 10.

#### c. Calibration

A beam-splitter arrangement interposed between the laser and the diaphragm allowed for a monitored measure of laser performance. The portion of the beam reflected from the beam-splitter, after a reflection from a magnesium oxide diffusing block, was directed onto a filtered FW-114-biplanar photo-diode with an electronic integrating

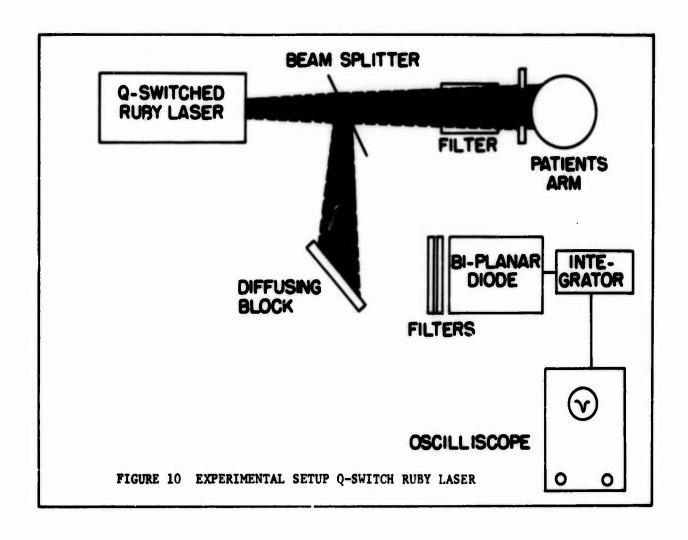




FIGURE 11 - EXPERIMENTAL SETUP OF O-SWITCHED RUBY LASER TESTS

circuit. The output from this device was observed in a Tetronix 585 oscilliscope. The integrated peak provided a direct voltage measure proportional to the total pulse energy. The readings of this device were then calibrated by determining the radiant energy passing through the hole in the metal diaphragm as measured by a Hadron-TRG cone calorimeter and Keithly Microvolt meter. radiant exposure (J/cm<sup>2</sup>) passing through the diaphragm was then calculated. The reproducibility of the overall system for a given charge level was +10%, hence, the calibration data was recorded as a function of the input charge level setting. Experimentally, the exposures were monitored on the oscilliscope to verify reproducibility of the predetermined radiant exposure levels. The overall experimental setup is shown in Figure 11. Laser charge levels were then selected which yielded radiant exposures ranging from 0.13 to 1.28 J/cm<sup>2</sup> at the diaphragm.

#### 6. Q-Switched Neodymium-Glass Laser

#### a. Laser Characteristics

2. Make: Spacerays

3. Model: 1010QDC2 - Oscillator-amplifier

4. Operation: Pockel cell Q-switched
Laser pulse: 75 nsec

5. Wavelength: 1060 nm

#### b. Delivery

The beam from a Q-switched neodymium-glass laser focused by a long focal length lens (FL=571 mm) onto a 1.05 cm hole in a metal diaphragm placed at a distance (approximately 200 cm) where the size of the focused spot at this point was approximately 2.5 cm in diameter. As a result, only the central portion of the beam passed through the hole and presented a nearly uniform radiant exposure to the skin surface. The basic arrangement is shown in Figure 12. For some exposures, where lower radiant exposures were required, the lens was removed - producing approximately a 50% reduction in the radiant exposure at the diaphragm.

#### c. Calibration

A beam-splitter arrangement interposed between the laser and the diaphragm allowed for a monitored measure of laser performance. The portion of the beam reflected

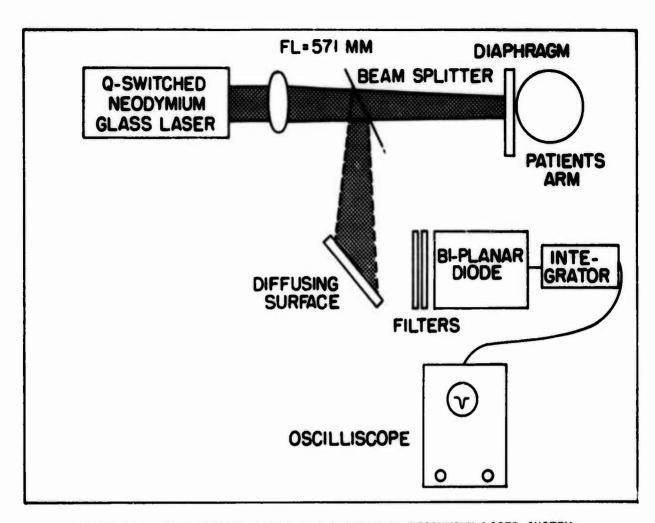


FIGURE 12 - EXPERIMENTAL SETUP FOR Q-SWITCHED NEODYMIUM LASER SYSTEM

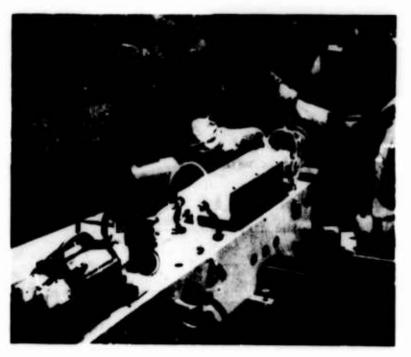


FIGURE 13 - EXPERIMENTAL SETUP FOR Q-SWITCHED NEODYMIUM LASER TESTS

from the beam-splitter after a reflection from a magnesium-oxide diffusing block, was directed onto a filtered FW-114 biplanar photo-diode with an electronic integrating circuit. The output from this device was observed on a Tetronix oscilliscope. The integrated peak provided a direct voltage measure proportional to the total pulse energy.

The readings of this device were then calibrated by determining the radiant energy passing through the hole in the metal diaphragm as measured by a Hadron-TRG cone calorimeter and Keithley Microvolt-meter. The radiant exposure (J/cm²) passing through the diaphragm was then calculated. The reproducibility of the overall system for a given charge level was ±10%, hence, the calibration data was recorded as a function of the input charge level setting. Experimentally, the exposures were monitored on the oscilliscope to verify the reproducibility of the predetermined radiant exposure levels. The overall experimental setup is shown in Figure 13.

Laser charge levels were then selected which yielded radiant exposures ranging from 2.3 to 8.8 J/cm² at the

diaphragm.

## B. Reflectance Measurements

Reflectance data of the flexor surface of the forearm were obtained for each patient using an IDL "Color Eye" reflectance spectrophotometer.

(Figure 14). This device measures the reflectance of the skin relative to a known diffuse reflection standard of magnesium oxide. The spectral range extends from 400 to 700 nm in 16 specific 20 nm steps.

The data obtained for all patients is given in Appendix A. For those lasers which emit in the visible spectra (400 to 700 nm), such reflectance data can give a first order approximation of the relative absorption in the tissues at a particular wavelength by subtracting the reflectance at that wavelength from 100%.

It is of note to comment on the performance of this device for measurement of spectral reflectance of human tissues. In the early phase of the study, a "Color Eye" device was tested in which the sampling port of the integrating sphere was smaller (1 cm<sup>2</sup>) than the unit which was eventually used (which had a 1 inch diameter port). It was argued that smaller sized port would more closely simulate the actual area of the skin to be eventually exposed by laser radiation on the human volunteers. The system was tested upon arrival on human skin and the results are shown in Figure 15 as curve A. Also shown, for comparison, are reflectance curves from the same individual previously done with two other devices. These are Curve B, using a "Color Eye" with large area view (1 inch aperature) and Curve C, using a General Electric Recording Electrospectrophotometer. Note the abrupt "fall off" in the reflectance values using the small area view "Color Eye" at wavelengths

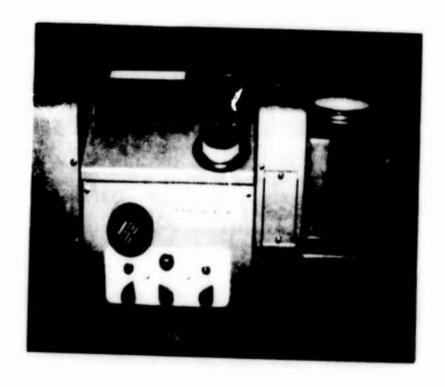


FIGURE 14 - IDL "COLOR EYE" USED FOR REFLECTANCE TESTS

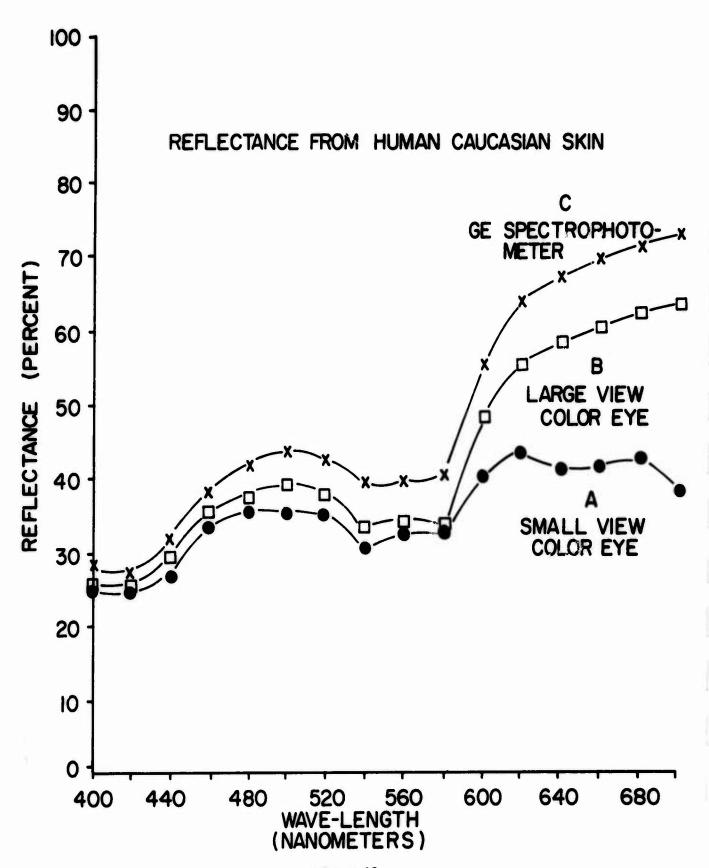


FIGURE 15

above 580 nm. In reviewing the literature on reflectance spectra from human subjects as well as comparing the previous data on this individual, the data using the small area view was obviously in error. It was suspected that the multiple scattering of light in tissues at visible wavelengths in the ranges 580-700 nm actually expand the effective areas of backscattered light peripherally to the edges of the integrating sphere aperture that captures the backscattered light, and, hence, a large percentage of the backscattered light is not returned into the integrating sphere for eventual measurement. This same effect is also present with the large area view (1 inch diameter), but due to the increased size of the sample area (approximately a factor of 6) the edge losses no longer predominate. Hence, we are able to obtain representative reflectance measurements using the large data area view "Color Eye". In comparison to the G.E. Recording Spectrophotometer, the small area view " "Color Eye" indicates a lower reflectance value which is nearly a constant 15 percent over the entire visible range. Since these two pieces of data were taken at least one-year apart, one can only speculate whether the difference is due to the instrument, or to pigment or to pigment variations resulting from sun exposure.

One cannot deduce the relative absorption in tissues at the 10,600 nm CO<sub>2</sub> laser wavelength, since this frequency does not fall within the measurement range of the "Color Eye" device. It is anticipated that all tissues - irrespective of visible color qualities - will display approximately the same absorption at the CO<sub>2</sub> laser frequency as would be obtained in water at a 10,600 nm wavelength. Fine (9), et al has estimated this to be approximately 95% absorption.

Simularly, one cannot directly deduce the relative absorption in tissues at the Nd-YAG wavelength of 1,060 nm with the data from the "Color Eye". Some relative estimate is possible by reference to the published work of Kuppenheim (7) which demonstrates the relative reflectance of Caucasian (light and darkly pigmented) and Negro skin. This data, as shown in Figure 16, indicates that one can expect up to 60% reflectance in lightly pigmented Caucasian, up to 50% reflectance in darkly pigmented Caucasian males, and up to 45% reflectance in Negro skin.

To a first approximation, due to the symmetry of the reflectance curves in the range from 700 nm to 1,100 nm, one can make some estimate of the absorption of tissues at 1,060 nm when the data at 700 nm is known.

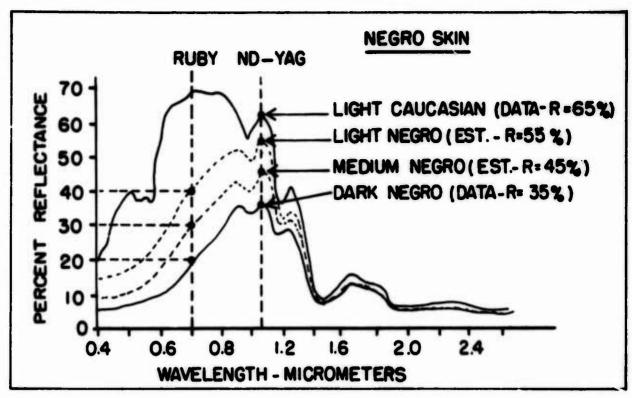
Using Kuppenheim's data, one can estimate the skin absorption at 1,060 nm as given in Table I.

TABLE I

SKIN ABSORPTION AT 1,060 nm

AS DETERMINED BY REFLECTANCE AT 700 nm

REFLECTANCE @ 700 nm (percent)	SKIN TYPE	REFLECTANCE @ 1,060 nm (percent)	ABSORPTION * @ 1,060 nm (percent)
70	Fair Caucasian	60	40
65	Medium Caucasian	55	45
55	Dark Caucasian	50	50
40	Light Negro	55	45
30	Medium Negro	45	55
20	Dark Negro	35	65



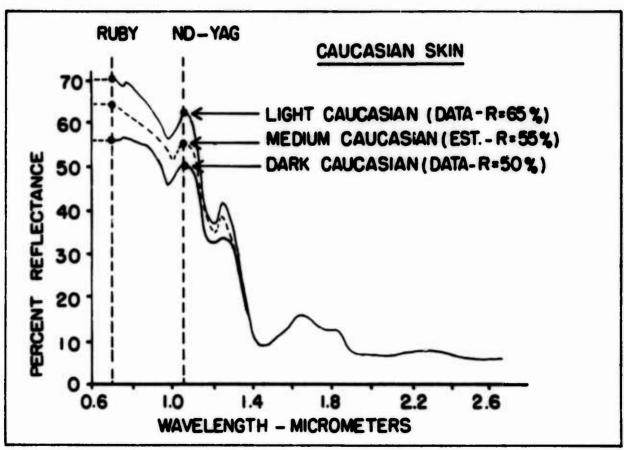


FIGURE 16

REFLECTANCE DATA OF KUPPENHEIM FOR ESTIMATING HUMAN SKIN REFLECTANCE AT 1.06 MICROMETERS

#### III PATIENT TREATMENTS AND RESULTS

The following will detail the exposure data and results of the 28 patients that were used in this study:

### 1. NORMAL MODE RUBY LASER SERIES

## A. Exposure Data of Caucasian Patients - Ruby Laser

PATIENTS: No. 1 (L.G.), No. 2 (J.B.), No. 7 (T.H.), No. 8 (T.D.)

DATES OF TREATMENT: October 5, 1972 - Patients No. 1 & 2

October 26, 1972 - Patients No. 7 & 8

## a. DESCRIPTION OF PATIENT No. 1

The patient (L.G.) is a sixty-seven year old Caucasian male. The site of irradiation was the flexor surface of the right forearm.

The patient had experienced repeated laser exposures for testing purposes on one small area of the right forearm that was not included in this test. A few small old scars were also present on the patient's arm, but these were not located in the areas to be irradiated. The reflectance data (Appendix A - Figure 1) at 700 nm indicated 61% reflectance, indicating approximately 39% of the incident ruby laser radiation would be absorbed by the skin.

## b. DESCRIPTION OF TREATMENT - PATIENT No. 1

Five exposures were made at each of the levels of 10, 15, 20, 25 and  $30 \text{ J/cm}^2$  for a total of 25 exposures.

Itching was immediately noted following irradiation at a radiant exposure of  $10 \text{ J/cm}^2$ , but no immediate visible reaction was noted in

this area, even up to ten minutes post-treatment, although the itching sensation persisted.

#### c. RESULTS - PATIENT No. 1

Reactions were recorded as given in Table II and Figure 17

TABLE II

POST-RUBY-LASER SKIN REACTIONS

PATIENT No. 1

RADIANT EXPOSURE (J/cm <sup>2</sup> )	REACTION AT** ONE-HOUR	REACTION AT 24 HOURS
10	0/5	2/5
15	3/5	5/5
20	3/5	5/5
25	4/5*	5/5
30	5/5	5/5

\*One large papule was noted in one of the 25 J/cm<sup>2</sup> doses.

The reaction of the skin of this patient was a formation of small red papules. This is in marked contrast to subsequest ruby laser exposures on other patients where the typical reaction was an erythema formation. A close-up of this papular reaction is shown in Figure 18. The patient at 24 hours indicated that severe itching persisted in the encire arm throughout the 24 hour period. In the areas irradiated at 10 J/cm<sup>2</sup>, two areas containing small red papules and faint erythema were observed at 24 hours post-exposure. (Figure 19) These areas measured 0.7 cm diameter. In regions irradiated at levels from 20 to

<sup>\*\*</sup>Notation: x/5 indicates x positive reactions at the time of examination



FIGURE 17 - PATIENT No. 1 - ONE-HOUR POST EXPOSURE



FIGURE 18 - PATIENT No. 1 - CLOSE-UP SHOWING PAPULAR REACTION AT ONE-HOUR

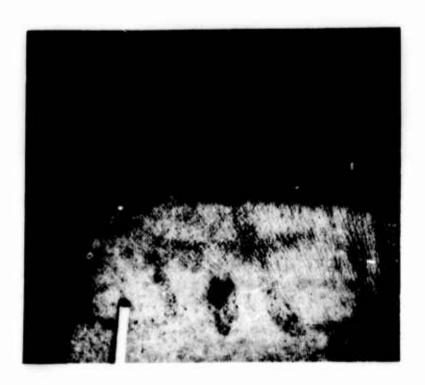


FIGURE 19 - PATIENT No. 1 - CLOSE-UP OF TWO PAPULES AT 24 HOURS

RESULTING FROM 10 J/cm<sup>2</sup> EXPOSURE.



FIGURE 20 - PATIENT No. 1 - 24 HOURS POST-EXPOSURE



FIGURE 21 - PATIENT No. 1 - 168 HOURS FOST-EXPOSURE

30 J/cm<sup>2</sup>, more intense papular reactions and small blisters were noted. The size in these areas measured about 1.8 cm (<u>larger</u> than beam size) with elevated pruritic areas. (Figure 20)

At 48 hours two areas irradiated at 10 J/cm<sup>2</sup> contained papules. All

At 96 hours (4 days) the irradiated areas were still uncomfortable and itching still persisted. No new papular areas were present.

At 168 hours (7 days) the irradiated areas were almost completely healed and scabs remained in only a few areas where the most severe reactions had occurred. (Figure 21)

This patient (LG) may be photosensitive to ruby laser since the reaction did <u>not</u> subside at 24 hours, and the presence of severe itching, papules and blisters indicate a more severe reaction than is normally encountered.

## d. DESCRIPTION OF PATIENT No. 2

other areas were blistered.

The patient (J.B.) is a twenty-seven year old Caucasian female who has been a subject of laser treatment for tattoos of the legs for one year. The site of the test exposures was the flexor surface of the right forearm. The reflectance data at 700 nm indicated 57% reflectance, hence, approximately 43% of the incident ruby laser radiation will be absorbed by the skin. (Appendix A - Figure 1)

# e. <u>DESCRIPTION</u> <u>OF TREATMENT</u> - <u>PATIENT</u> <u>No. 2</u>

Five exposures were made at each of the levels of 10, 15, 20, 25 and  $30\ \mathrm{J/cm}^2$  for a total of 25 exposures.

No immediate sensations were noted by the patient. Some slight itching was described approximately 30 minutes post-treatment which disappeared altogether at one-hour post-treatment.

All areas exposed at and above  $15 \text{ J/cm}^2$  showed a definite red erythema at 10 minutes post-irradiation which persisted through the one-hour post-treatment examination.

## f. RESULTS - PATIENT No. 2

Reactions were recorded as given in Table III and Figure 22.

TABLE III

POST-RUBY-LASER SKIN REACTIONS

PATIENT No. 2

RADIANT EXPOSURE (J/cm <sup>2</sup> )	REACTION AT ONE-HOUR	REACTION AT 24 HOURS
10	1/5	0/5
15	5/5	5/5
20	5/5	5/5
25	5/5	5/5
30	5/5	3/5

The reaction in this patient is a near uniform erythema with no papules present. At 24 hours the reaction at 10 and 20  $J/cm^2$  (the edge rows) were faint and two had completely disappeared in the 30  $J/cm^2$  row. There was one small papule on the edge of the remaining spots in the 30  $J/cm^2$  row, although it should be noted that two of the erythema spots



FIGURE 22 - PATIENT No. 2 - ONE-HOUR POST-EXPOSURE



FIGURE 23 - PATIENT No. 2 - 24 HOURS POST-EXPOSURE

had already disappeared in this row. (See Figure 23) No itching or discomfort was noted during the one-hour/24 hour period. Follow up on this patient was not possible beyond 24 hours.

## g. DESCRIPTION OF PATIENT No. 7

The patient (T.H.) is a 44 year old Caucasian male who has been a subject for laser treatment of a large tattoo of the mesial aspect of the right arm for over four years. The site of the test exposures was the flexor surface of the left forearm. The reflectance data at 700 nm indicated 52% reflectance, hence, approximately 48% of the incident ruby laser radiation will be absorbed by the skin.

(Appendix A - Figure 1)

## h. DESCRIPTION OF TREATMENT - PATIENT No. 7

Five exposures were made at each of the levels of 5, 10, 15, 20 and 25 J/cm<sup>2</sup> for a total of 25 exposures.

No immediate sensations were noted by the patient. Some slight sensations (itching) was described at one-hour post-exposure. No immediate reactions were noted during an examination at five-minutes post-exposure.

#### 1. RESULTS - PATIENT No. 7

Reactions were recorded as given in Table IV and Figure 24.



FIGURE 24 - PATIENT #7 - ONE-HOUR POST-EXPOSURE

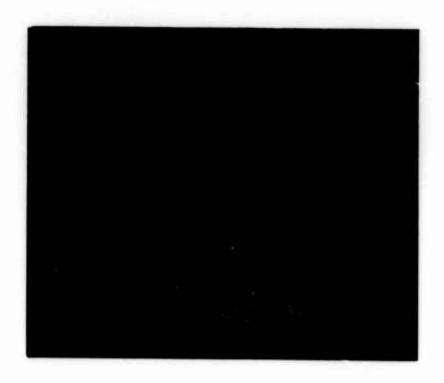


FIGURE 25 - PATIENT #8 - ONE-HOUR POST EXPOSURE

TABLE IV
POST-RUBY-LASER SKIN REACTIONS

#### PATIENT No. 7

RADIANT EXPOSURE (J/cm <sup>2</sup> )	REACTION AT ONE-HOUR	REACTION AT 24 HOURS
5	0/5	0/5
10	3/5	2/5
15	4/5	4/5
20	4/5	4/5
25	5/5	5/5

The reaction in this patient was a mild erythema at one-hour. (The 24 hour follup up photograph is not available due to a camera malfunction.)

## j. DESCRIPTION OF PATIENT No. 8

The patient (T.D.) is a seventy-year old Caucasian male who has been a subject for laser treatment of skin cancers and other skin lesions of the head and back for over nine years. The site of the test exposures was the flexor surface of the right forearm. The reflectance data at 700 nm indicated 62% of reflectance, hence, approximately 38% of the incident ruby laser radiation will be absorbed by the skin. (Appendix A - Figure 1)

## k. DESCRIPTION OF TREATMENT - PATIENT No. 8

Five exposures were made at each of the levels of 5, 10, 15, 20 and  $25 \text{ J/cm}^2$  for a total of 25 exposures.

The sensations of the exposures as described by the patient are summarized in Table V. This commentary of the patient is included to reinforce one conclusion of the study, namely, that exposures near the MRD<sub>50</sub> levels are all mildly painful. Hence, someone accidently exposed at these levels would most porbably have a reflex reaction to move his exposed skin from the beam.

TABLE V

COMMENTS BY PATIENT No. 8

#### ON RUBY LASER EXPOSURES OF THE SKIN

RADIANT EXPOSURE	COMMENTS
(J/cm <sup>2</sup> )	
5	"No sensation at all."
10	"Almost no sensation."
15	"Felt reaction, but not severe."
20	"Definitely felt reaction."
25	"Definite reaction, but still not bad."

No immediate one-hour reactions were described by the patient.

# 1. RESULTS - PATIENT No. 8

Reactions were recorded as given in Table VI and Figure 25.

TABLE VI
POST-RUBY-LASER SKIN REACTIONS

#### PATIENT No. 8

R	ADIANT EXPOSURE	REACTION AT	REACTION AT
	(J/cm <sup>2</sup> )	ONE-HOUR	24 HOURS
	5	0/5	0/5
	10	0/5	0/5
	15	3/5	1/5
	20	5/5	2/5
	25	5/5	4/5

The reaction in this patient was spotty papules at one-hour. The 24 hour follow up photograph is not available due to a camera ma function.

### B. Exposure Data of Negro Patients - Ruby Laser

PATIENTS: No. 9 (I.H.) and No. 16 (S.H.)

DATES OF TREATMENT: January 4, 1973 Patient No. 9

February 8, 1973 Patient No. 16

March 19, 1973 Patients No. 9 & 16

March 20, 1973 Patient No. 16

## a. DESCRIPTION OF PATIENT No. 9

The patient (I.H.) is a thirty year old Negro male volunteer. The site of the irradiation was the flexor surface of the right forearm.

The reflectance data (Appendix A - Figure 2) at 700 nm yielded a value of 30%, indicating approximately 70% of the incident ruby laser radiation would be absorbed by the skin.

## b. DESCRIPTION OF TREATMENT - PATIENT No. 9

Five exposures were made at each of the levels of 1.5, 1.75, 2.0 (in session two) and 3.0, 4.0, 6.0 and 8  $J/cm^2$ , (in session one) for a total of 40 exposures on two separate occasions.

No itching was noted following any of the doses including the highest of  $8 \text{ J/cm}^2$ . An immediate visible reaction was noted in all areas irradiated at and above  $3.0 \text{ J/cm}^2$ . (See Figure 31)

## c. RESULTS - PATIENT No. 9

Reactions were recorded as given in Table VII. and Figure 26.

TABLE VII

POST-RUBY-LASER SKIN REACTIONS

### PATIENT No. 9

	RADIANT EXPOSURE (J/cm <sup>2</sup> )	REACTION AT FIVE-MINUTES	REACTION AT ONE-HOUR	REACTION AT 24 HOURS
	1.5	0/5	0/5	0/5
SESSI	ON 1.75	0/5	0/5	0/5
II	2.0*	0/10	4/10	4/10
	3.0	0/5	5/5	5/5
SESSI	ON 4.0	0/5	5/5	5/5
I	6.0	0/5	5/5	5/5
	8.0	0/5	5/5	5/5

\*10 doses given on two treatment sessions at this level

The reaction of this patient was an erythema indicated by an immediate darkening of the tissues. A close-up of this reaction is shown in Figure 27.

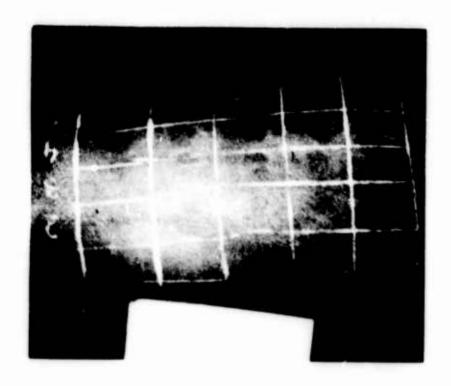


FIGURE 26 - PATIENT No. 9 - FIVE-MINUTES POST-EXPOSURE (Session I). NOTE

RAISED LESIONS IN ROW 3 (6J/cm<sup>2</sup>) AND ROW 4 (8 J/cm<sup>2</sup>)

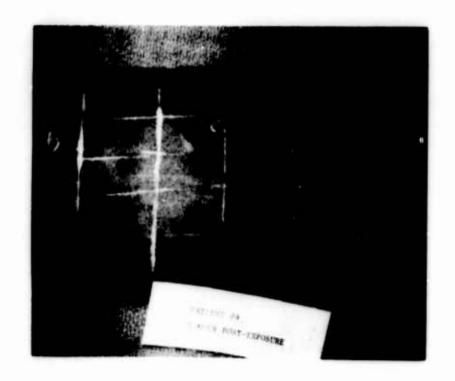


FIGURE 27 - PATIENT NO. 5 - ONE-HOUR POST-EXPOSURE (Session I).

NOTE BLISTERED REACTION IN ROW 4 (8 J/cm<sup>2</sup>)



FIGURE 28 - PATIENT No. 9 - THO-NEEKS POST-EXPOSURE (Session 1). NOTE HEAVY HEALING AND DEPIGMENTATION OF SKIN.

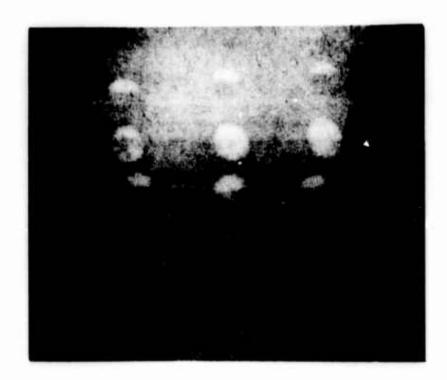


FIGURE 29 - PATIENT NO. 9 - ONE-MONTH POST-EXPOSURE (Session 1). NOTE SMOOTH HEALING AND BEGINNING OF REPIGMENTATION IN LESION AREAS.

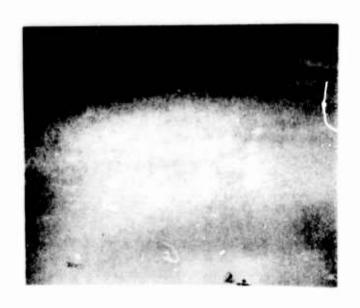


FIGURE 30 - PATIENT No. 9 - FOURTEEN-MONTHS POST-EXPOSURE.

NOTE REPIGMENTATION HAS NEARLY COVERED AREAS

PREVIOUSLY VOID OF PIGMENT.

The patient at 24 hours indicated that no itching occurred during the 24 hour period. Severe blisters were noted in the areas irradiated at 8 J/cm<sup>2</sup>. (Figure 27) In regions irradiated at levels 3.0, 4.0 and 6.0 J/cm<sup>2</sup> less intense reactions and blisters were noted. The size in these areas measured about 1.8 cm (<u>larger</u> than beam size) with elevated pruritic areas.

At two weeks, the irradiated areas had begun to heal leaving depigmented regions. (Figure 28)

At four weeks, the irradiated areas continued to heal and repigmentation had set in. (Figure 29)

At two months, the irradiated areas were completely healed and repigmentation had continued to progress in the scarred area.

At fourteen months, the repigmentation had nearly covered these areas previously void of pigment. (Figure 30)

#### d. DESCRIPTION OF PATIENT No. 16

The patient (S.H.) is a forty-three year old Negro male volunteer.

The site of the test exposures was the flexor surface of the right and left forearm. The reflectance data at 700 nm indicated 41% reflectance, hence, approximately 59% of the incident ruby laser radiation will be absorbed by the skin. (Appendix A - Figure 2)

## e. DESCRIPTION OF TREATMENT - PATIENT No. 16

Five exposures were made at each of the levels of 0.5, 0.75, 1.25, 1.75, 2.25, 2.50, 2.75, 3.0, 3.25, 4.5, 6.0, 7.0, 8.0 during three

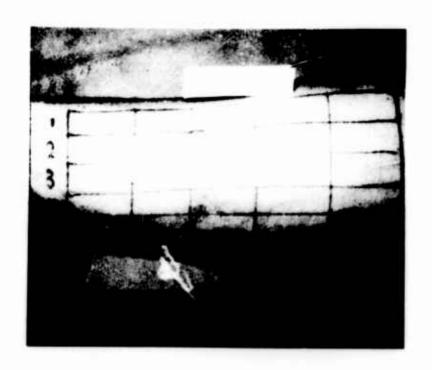


FIGURE 31 - PATIENT No. 16 - ONE-HOUR POST-EXPOSURE (Session 1).

NOTE NO REACTIONS UP TO 2.25 J/cm<sup>2</sup> (ROW 5).

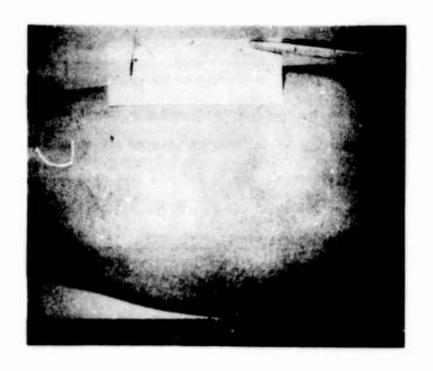


FIGURE 32 - PATIENT No. 16 - TWENTY-FOUR HOURS POST-EXPOSURE (Session III).

NOTE REACTIONS IN BOTH ROWS AT 7.0 J/cm<sup>2</sup> AND 8.0 J/cm<sup>2</sup>.

separate sessions for a total of 65 exposures.

No immediate sensations were noted by the patient except at 7.0 and  $8.0 \, \mathrm{J/cm}^2$ .

All areas exposed at  $8 \text{ J/cm}^2$  showed a definite erythema at five-minutes post-irradiation which persisted through the one-hour post-treatment examination.

# f. RESULTS - PATIENT No. 16

Reactions were recorded as given in Table VIII.

TABLE VIII

POST-RUBY-LASER SKIN REACTIONS

PAT	<b>TIENT</b>	No	16

	RADIANT EXPOSURE	REACTION AT	REACTION AT	REACTION AT
	(J/cm <sup>2</sup> )	FIVE MINUTES	ONE -HOUR	24 HOURS
	0.50	0/5	0/5	0/5
	0.75	0/5	0/5	0/5
SESSION	1.25	0/5	0/5	0/5
1	1.75	0/5	0/5	0/5
	2.25	0/5	0/5	0/5
	2.50	0/5	0/5	0/5
	2.75	0/5	0/5	0/5
SESSION	3.00	0/5	0/5	0/5
II	3.25	0/5	0/5	0/5
	4.50	0/5	0/5	0/5
	6.00	0/5	0/5	0/5
SESSION	7.00	3/5	4/5	5/5
III	8.00	5/5	5/5	5/5

No reactions were seen in the first session exposures (2.25 J/cm<sup>2</sup> or less). Subsequent exposures were done at levels: 2.5 - 6.0 J/cm<sup>2</sup> (Session II). The reaction in this patient was uniform erythema with no papules present. No itching or discomfort was noted during the one-hour/24 hour period.

Additional exposures were done at levels: 7.0 and 8.0  $J/cm^2$  (Session III). Exposures at these levels gave reactions at both one-hour and at 24 hours (Figure 32).

C. Normal mode ruby laser series data analysis of Caucasian patients

Analysis of the data given in Tables II, III, IV, and VI for patients

No. 1, No. 2, No. 7, and No. 8 was done by constructing probability

curves for each patient. The data are presented in Figure 33.

The data yielded a 50% probability for producing a minimal reaction

ranging from 11 to 20 J/cm<sup>2</sup>.

Comparison of the MRD values to the skin absorption data is given in

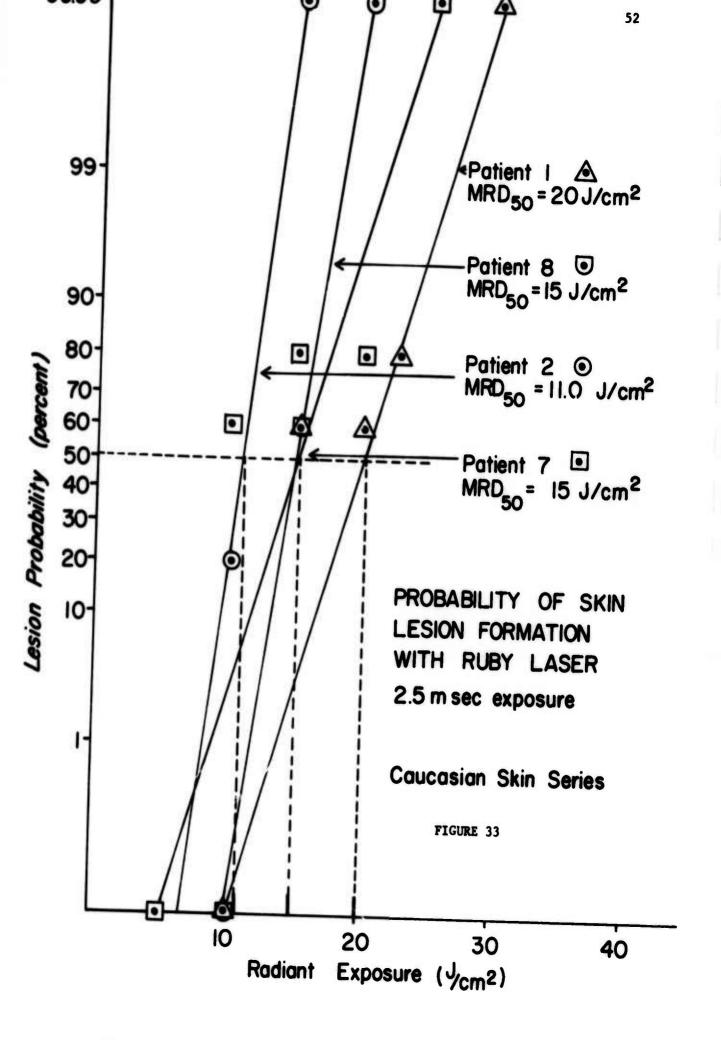
Table IX.

TABLE IX
SUMMARY OF CAUCASIAN SKIN ABSORPTION DATA

## RUBY LASER SERIES

PATIENT	PERCENT	MRD <sub>50</sub>	ABSORBED DOSE
NUMBER	ABSORPTION	$(J/cm^2)$	$(J/cm^2)$
1	39	20	7.8
2	43	11	4.7
7	48	15	7.2
8	38	15	5.7

As previously discussed, patient No. 1 displayed a severe reaction to the ruby laser irradiation, implying, perhaps, photosensitization. It is of note, that the MRD $_{50}$  level was 1.5 to 2.0 times larger than the other patients tested. Review of the patient No. 1 data at 24 hours



will show that this patient displayed reactions at radiant exposures of one-half the magnitude of the one-hour  $MRD_{50}$ . However, in order to be consistant with the one-hour criteria for the  $MRD_{50}$  which was used throughout this study the 24 hour data was not assessed for the  $MRD_{50}$  criteria for this patient.

The increased reactivity at 24 hours is, possibly, dependent upon a photosensitization of the patient's skin which has apparently developed over many years, following many hundreds of deliberate exposures of pulsed ruby laser radiation at 694 nm. The purpose of these exposures was to attempt to induce increased reaction in the skin at this specific wavelength in an atopic individual.

Apparently this has been successful as detailed in the literature. (10)

This patient has, over the past eight years, received doses of pulsed ruby laser irradiation nearly everyday at levels ranging from 14 to 20 J/cm<sup>2</sup>. Over this time period the reaction in the skin has changed from a mild erythema to a papule formation and an occasional vesicle and severe itching in the 24 hour period following irradiation. This would indicate a form of sensitization to the laser exposure.

D. Normal mode ruby laser series data analysis of Negro patients

Analysis of the data given in Tables VII and VIII for patients No. 9

and No. 16 was done by constructing probability curves for each

patient. This data is presented in Figure 34.

The data yielded a 50% probability for producing a minimal reaction

(MRD<sub>50</sub>) ranging from 2.2 J/cm<sup>2</sup> for darkly complected Negro skin

(patient No. 9, reflectance: 30%) and 7.0 J/cm<sup>2</sup> for lightly complected Negro skin (patient No. 16, reflectance: 41%).

Comparison of the MRD values to the skin absorption data is given in Table X.

TABLE X

SUMMARY OF NEGRO SKIN ABSORPTION DATA

RUBY LASER SERIES

PATIENT	PERCENT	MRD <sub>50</sub>	ABSORBED DOSE
NUMBER	ABSORPTION	$(J/cm^2)$	(J/cm <sup>2</sup> )
9	70	2.2	1.5
16	59	7.0	4.1

This data would indicate that the absorbed dose required to produce a minimal reaction decreases as the absorption increases. For example, the data shows that up to two times <u>less</u> absorbed energy is required to produce a minimal reaction in the darkly pigmented Negro than in the lighter pigmented Negro skin. Since the absorption occurs principally in the pigment layer near the surface of the skin, the results would indicate that less tissue volume is involved in reactions in the darker pigmented skin. Hence, less energy is required to produce a reaction.

## 2. ARGON LASER SERIES

## A. Exposure Data of Caucasian Patients - Argon Laser

PATIENTS: No. 3 (L.G.), No. 4 (J.Z.), No. 5 (G.C.), No. 6 (R.H.)

DATE OF TREATMENT: October 19, 1972

## a. DESCRIPTION OF PATIENT No. 3

The patient (L.G.) is a sixty-seven year old Caucasian male. The site of the irradiation was the mesial surface of the left upper arm. This area was chosen to obtain to a significantly lower value of absorption at this laser frequency. Also, this patient had previously experienced ruby laser exposures on the right forearm for testing purposes. The reflectance data (Appendix A - Figure 3) at 500 nm indicated 45% reflectance, indicating approximately 55% of the incident argon laser radiation would be absorbed by the skin.

### b. DESCRIPTION OF TREATMENT - PATIENT No. 3

Five exposures were made at each of the levels of 4.4, 5.5, 6.6, 8.3, and  $10 \text{ J/cm}^2$  for a total of 25 exposures.

An immediate visible reaction was noted only in the areas irradiated at a radiant exposure of  $10 \text{ J/cm}^2$ . (Figures 35-36) No itching or other sensations were noted.

### c. RESULTS - PATIENT No. 3

Reactions were recorded as given in Table XI and Figure 37.

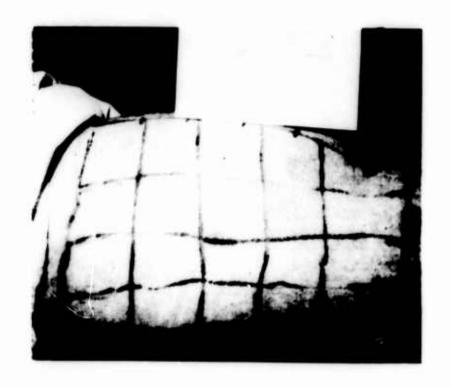


FIGURE 35 - PATIENT No. 3 - FIVE MINUTES POST-EXPOSURE

REACTIONS CLEARLY EVIDENT IN ROW 5 (10 J/cm<sup>2</sup>)



FIGURE 36 - PATIENT No. 3 - CLOSE-UP OF REACTION IN ROW 5

AT FIVE-MINUTES POST-EXPOSURE (10 J/cm<sup>2</sup>)

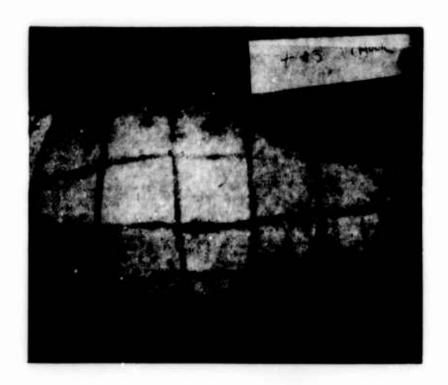


FIGURE 37 - PATIENT No. 3 - SHOWING REACTIONS AT ONE-HOUR POST-EXPOSURE.

MILD REACTIONS IN ROW 4 NOT CLEARLY EVIDENT IN PHOTO.

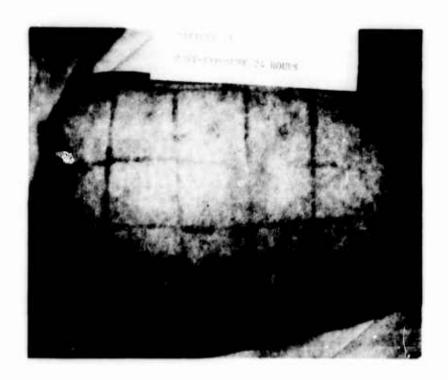


FIGURE 38 - PATIENT No. 3 - REACTION AT 24 HOURS POST-EXPOSURE
REACTIONS AT 10 J/cm<sup>2</sup> STILL PRESENT

TABLE XI
POST-ARGON LASER SKIN REACTIONS

#### PATIENT No. 3

RADIANT EXPOSURE (J/cm <sup>2</sup> )	REACTION AT ONE-HOUR	REACTION AT 24 HOURS
4.4	0/5	0/5
5.5	0/5	0/5
6.6	0/5	0/5
8.3	2/5	0/5
10.0	5/5	5/5

The reaction of this patient was the formation of large papules. A close-up photograph of this papular reaction is shown in Figure 38.

The patient at 24 hours indicated that absolutely no itching occurred in the arm during any of the 24 hour period. This was contrary to his previous reactions following ruby laser exposures. All five areas contained small red papules and faint erythema. (Figure 38) These areas measured approximately 0.5 cm diameter.

At 96 hours (4 days) the  $10 \text{ J/cm}^2$  areas were still visible and their size was slightly larger (Figure 39).

Previous testing of this patient (L.G.) had indicated he may be photosensitive to ruby laser irradiation since reactions of this modality did <u>not</u> reside at 24 hours and the presence of severe itching, papules and blisters demonstrated a more severe reaction than is normally encountered. Such reactions were <u>not</u> seen with the argon

laser, indicating a high probability that a wavelength specific response is the cause for the ruby laser reactions.



FIGURE 39 - PATIENT No. 3 - FOUR DAYS POST-EXPOSURE

#### d. DESCRIPTION OF PATIENT No. 4

The patient (J.Z.) is a fifty-seven year old caucasian female who has been a subject of ruby laser treatment for various skin lesions for over one-year. The site of the test exposures was the flexor surface of the right forearm. The reflectance data at 500 nm indicated 30% reflectance, hence approximately 70% of the incident argon laser radiation will be absorbed by the skin (Appendix A - Figure 3)

## e. DESCRIPTION OF TREATMENT - PATIENT No. 4

Five exposures were made at each of the levels of 4.2, 4.8, 5.6, 6.5, and  $7.6 \text{ J/cm}^2$  for a total of 25 exposures. No immediate sensations were noted by the patient.

All areas exposed 6.5 and 7.6  $J/cm^2$  showed a definite red erythema at five-minutes post-irradiation which persisted through the one-hour post-treatment examination. (Figures 40 and 41)

#### f. RESULTS - PATIENT No. 4

Reactions were recorded as given in Table XII and Figures 42 and 43.

TABLE XII

POST-ARGON-LASER SKIN REACTIONS

PATIENT No. 4

ROW ON ARM	RADIANT EXPOSURE (J/cm <sup>2</sup> )	REACTION AT ONE HOUR	REACTION AT
1	4.2	0/5	1/5
5	4.8	0/5	0/5
2	5.6	0/5	2/5
3	6.5	3/5	4/5
4	7.6	5/5	5/5

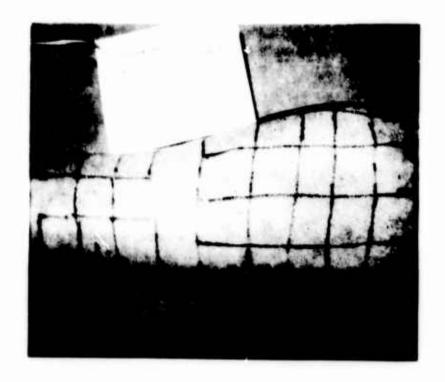


FIGURE 40 - PATIENT No. 4 - SHOWING REACTIONS AT FIVE MINUTES POST-EXPOSURE REACTIONS IN ROWS 3 (6.5 J/cm<sup>2</sup>) and ROW 4 (7.6 J/cm<sup>2</sup>) CLEARLY EVIDENT.



FIGURE 41 - PATIENT No. 4 - CLOSE-UP OF REACTION AT 5.6 J/cm<sup>2</sup> AT FIVE MINUTES
THIS DISAFPEARED AT ONE-HOUR EXAMINATION



I

FIGURE 42 - PATIENT No. 4 - ONE-HOUR POST-EXPOSURE. REACTION OBSERVED ONLY IN ROW 3 (6.5 J/cm<sup>2</sup>) AND ROW 4 (7.6 J/cm<sup>2</sup>)

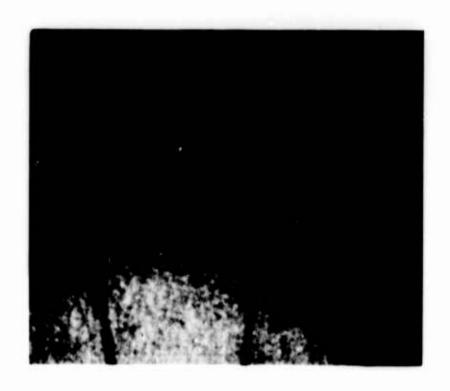


FIGURE 43 - PATIENT No. 4 - ONE-HOUR POST-EXPOSURE

CLOSE-UP OF REACTION AT 7.6 J/cm<sup>2</sup> (ROW 4)

The one-hour reaction in this patient was a near uniform erytherma. At 24 hours a few reactions at 4.2 and 5.6  $J/cm^2$  had now become visible, although no reactions were observed at 4.8  $J/cm^2$ . (Figure 44) No itching or discomfort was noted during the one-hour/24 hour period.



FIGURE 44 - PATIENT No. 4 - EXAMINATION AT 24 HOURS POST-EXPOSURE

## g. DESCRIPTION OF PATIENT No. 5

The patient (G.C.) is a fifty-eight year old Caucasian male who has been a subject for ruby and argon laser treatment of tattoos of the mesial aspect of the right arm, and facial angiomas for over six years. The site of the test exposures was the flexor surface of the left forearm. The reflectance data at 500 nm indicated 26% reflectance, hence, approximately 74% of the incident argon laser radiation will be absorbed by the skin. (Appendix A - Figure 3)

#### h. DESCRIPTION OF TREATMENT - PATIENT No. 5

Five exposures were made at each of the levels of 3.5, 4.1, 4.4, 5.1, and  $6.9 \text{ J/cm}^2$  for a total of 25 exposures. No immediate sensations were noted by the patient. Immediate reactions (five-minute examination) were observed only in the areas irradiated at  $6.0 \text{ J/cm}^2$  during an examination at five-minutes post-exposure. (Figure 45 and 46)

#### i. RESULTS - PATIENT No. 5

Reactions were recorded as given in Table XIII and Figure 47.

TABLE XIII
POST-ARGON LASER SKIN REACTIONS

#### PATIENT NO. 5

RADIANT EXPOSURE	REACTION AT	REACTION AT
(J/cm <sup>2</sup> )	ONE HOUR	24 HOURS
3.5	0 5	0/5
4.1	0/5	1/5
4.4	0/5	0/5
5.1	3/5	3/5
6.0	5/5	5/5

The one-hour reaction in this patient was a papular reaction in the irradiated areas as shown in Figure 47. The twenty-four hour examination revealed approximately the same result as the one-hour examination (Figure 48). One small reaction did appear in an area irradiated at  $4.1 \text{ J/cm}^2$ .



FIGURE 45 - PATIENT No. 5 - FIVE-MINUTES POST-EXPOSURE REACTIONS AT 5.1  $J/cm^2$  (ROW 2) AND 6.0  $J/cm^2$  (ROW 3) CLEARLY EVIDENT.



FIGURE 46 - PATIENT No. 5 - FIVE-MINUTES POST-EXPOSURE AT 5.1 J/cm<sup>2</sup>

CLOSE-UP OF ERYTHEMA WITH DIASCOPE USED TO DEPRESS SKIN

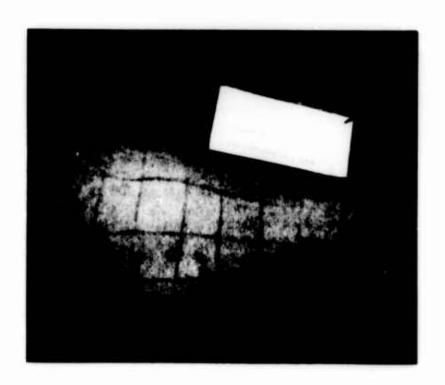


FIGURE 47 - PATIENT No. 5 - ONE-HOUR POST-EXPOSURE. ROW 3 (6.0 J/cm<sup>2</sup>)

STILL EVIDENT. THREE LESIONS ALSO PRESENT IN ROW 2 (5.1 J/cm<sup>2</sup>)

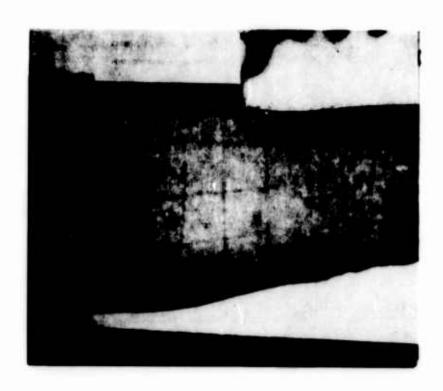


FIGURE 48 - PATIENT NO. 5 - 24 HOURS POST-EXPOSURE

#### j. DESCRIPTION OF PATIENT No. 6

The patient (R.H.) is a forty-nine year old Caucasian male who has been a subject for ruby laser treatment of facial angiomas for over four years. The site of the test exposures was the flexor surface of the right forearm. The reflectance data at 500 nm indicated 25% of reflectance, hence, approximately 75% of the incident argon laser radiation will be absorbed by his skin. (Appendix A - Figure 3)

## k. <u>DESCRIPTION</u> OF <u>TEST</u> <u>EXPOSURE</u> - <u>PATIENT No. 6</u>

Five exposures were made at each of the levels of 3.5, 4.0, 4.4, 5.6, and  $6.7 \text{ J/cm}^2$  for a total of 25 exposures

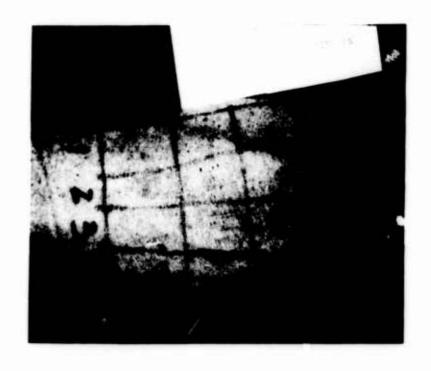


FIGURE 49 - PATIENT No. 6 - FIVE MINUTES POST-EXPOSURE

REACTIONS CLEARLY EVIDENT IN ROW 2 (5.6 J/cm<sup>2</sup>)

# 1. RESULTS - PATIENT No. 6

Reactions were recorded as given in Table XIV and Figure 50.

TABLE XIV

# POST-ARGON LASER SKIN REACTIONS PATIENT No. 6

RADIANT EXPOSURE (J/cm <sup>2</sup> )	REACTION AT ONE HOUR	REACTION AT 24 HOURS
3.5	0/5	0/5
4.0	3/5	1/5
4.4	5/5	5/5
5.6	5/5	5/5
6.7	5/5	5/5

The one-hour reaction in this patient was a series of small raised hemorrhagic punctum spots with white centers. The examination at 24 hours showed a severe reaction at levels 4.4 J/cm<sup>2</sup> and above.

Only one small area was observable at 4.0 J/cm<sup>2</sup>. (Figure 52)

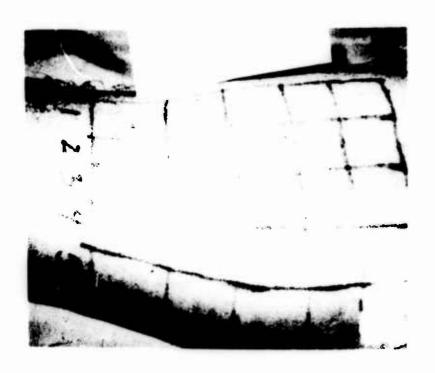


FIGURE 50 - PATIENT No. 6 - ONE-HOUR POST-EXPOSURE

DEFINITE LESIONS OBSERVABLE IN ROW 1 (4.4 J/cm<sup>2</sup>),

ROW 2 (5.6 J/cm<sup>2</sup>), AND ROW 3 (6.7 J/cm<sup>2</sup>). THREE

MILD LESIONS ALSO OBSERVABLE IN ROW 5 (4.0 J/cm<sup>2</sup>)

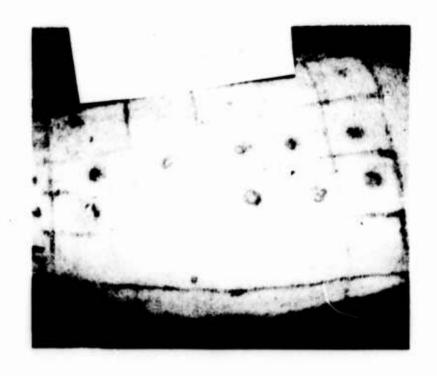


FIGURE 51 - PATIENT No. 6 - SHOWING SEVERE REACTIONS IN ROWS

1, 2, and 3 AT 24 HOURS POST-EXPOSURE

## B. Exposure data of Negro patients - Argon Laser

PATIENTS: No. 10 (I.H.), No. 11 (A.H.)

DATES OF TREATMENT: January 18, 1973 - Patients No. 10 & 11

January 31, 1973 - Patients No. 10 & 11

March 28, 1973 - Patients No. 10 & 11

#### a. DESCRIPTION OF PATIENT No. 10

The patient (I.H.) is a thirty year old Negro male volunteer. The site of irradiation was the flexor surface of the left forearm. The reflectance data (Appendix A - Figure 4) at 500 nm indicated 9% reflectance, indicating approximately 91% of the incident argon laser radiation would be absorbed by the skin.

## b. DESCRIPTION OF TREATMENT - PATIENT No. 10

Five exposures were made at each of the levels of 0.25, 0.5, 0.75, 1.0, 1.25, 2.5, 3.0, 4.0, and 5.0  $\rm J/cm^2$  for a total of 45 exposures. An immediate visible reaction was noted only in the areas irradiated at or above a radiant exposure of 4.5  $\rm J/cm^2$  (Figures 52-53). The patient described a definite "burn" sensation at the level of 3.0  $\rm J/cm^2$ , although no visible reaction was noted at this level.

## c. RESULTS - PATIENT No. 10

Reactions were recorded as given in Table XV and Figures 54 and 55.

TABLE XV
POST-ARGON-LASER SKIN REACTIONS

#### PATIENT No. 10

	RADIANT EXPOSURE	REACTION AT	REACTION AT	REACTION AT	
	(J/cm <sup>2</sup> )	FIVE MINUTES	ONE-HOUR	24 HOURS	
	0.25	0/5	0/5	0/5	
SESSION	0.5	0/5	0/5	0/5	
I	0.75	0/5	0/5	0/5	
•	1.0	0/5	0/5	0/5	
	1.25	0/5	0/5	0/5	
SESSION II	2.5	0/5	0/5	0/5	
	3.0	0/5	0/5	0/5	
SESSION	4.0	2/5	0/5	0/5	
III	5.0	5/5	5/5	5/5	

The reaction of this patient was an erythematous - papular area which was approximately 80% of the size of the 1.05 cm diameter aperature used to define the beam size.

The patient indicated that absolutely no itching occurred in the arm during any of the 24 hour period. Only the lesions at  $5 \text{ J/cm}^2$  were present at the 24 hour examination. (Figure 55)

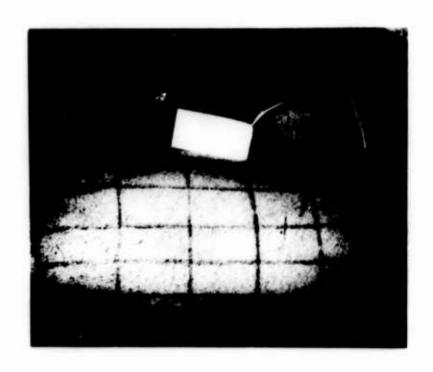


FIGURE 52 - PATIENT No. 10 - FIVE MINUTES POST-EXPOSURE - SESSION I  $(0.25 - 1.25 \text{ J/cm}^2)$  No reactions noted.

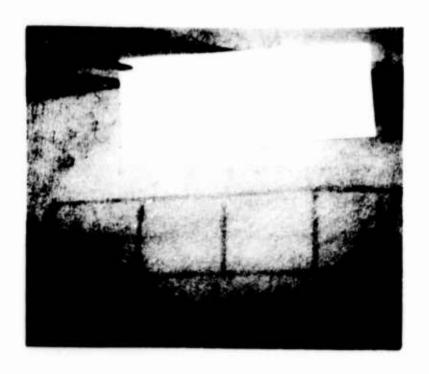


FIGURE 53 - PATIENT No. 10 - FIVE-MINUTES POST-EXPOSURE - SESSION II

(2.5 J/cm<sup>2</sup>) NO REACTIONS NOTED.

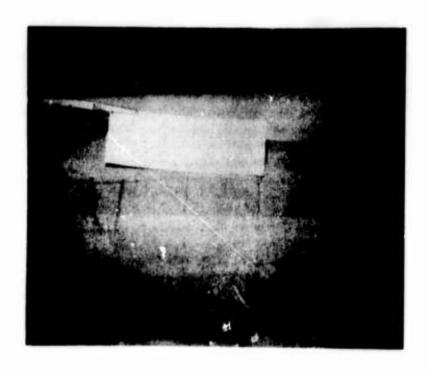


FIGURE 54 - PATIENT No. 10 - REACTION AT ONE-HOUR POST-EXPOSURE SESSION III.

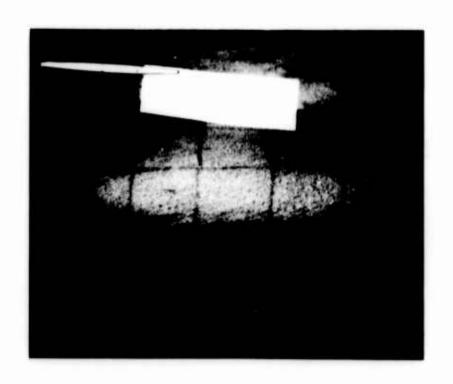


FIGURE 55 - PATIENT No. 10 - REACTION AT 24 HOURS POST-EXPOSURE

(Session III) NOTE DEFINITE REACTIONS IN ROW 3

(5 J/cm<sup>2</sup>)

#### d. DESCRIPTION OF PATIENT No. 11

The patient (A.H.) is a thirty-three year old Negro male. The site of the test exposures were given to the flexor surface of the right arm and left forearm. The reflectance data at 500 nm indicated 25% reflectance, hence, approximately 75% of the incident argon laser radiation will be absorbed by the skin. (Appendix A - Figure 4)

#### e. DESCRIPTION OF TEST EXPOSURES - PATIENT No. 11

Five exposures were made at each of the levels of 0.5, 1.0, 1.5, 2.0, 2.5, 3.5, 4.5, 5.5, and 6.5 J/cm<sup>2</sup> for a total of 45 exposures.

Areas exposed at and above 4.5 J/cm<sup>2</sup> showed in all or in part, immediate red papule formation five-minutes post-irradiation which completely disappeared at 15 minutes at all levels except 6.5 J/cm<sup>2</sup>. Irradiation sensation to 6.5 J/cm<sup>2</sup> was very painful, and an immediate redness developed at this exposure. (See Figure 56)

## f. RESULTS - PATIENT No. 11

Reactions were recorded as given in Table XVI

TABLE XVI

POST-ARGON-LASER SKIN REACTIONS

PATIENT No. 11

	RADIANT EXPOSURE	REACTION AT	REACTION AT	REACTION AT	
	$(J/cm^2)$	FIVE-MINUTES	ONE-HOUR	24 HOURS	
	0.5	0/5	0/5	0/5	
	1.0	0/5	0/5	0/5	
SESSION I	1.5	0/5	0/5	0/5	
	2.0	0/5	0/5	0/5	
	2.5	0/5	0/5	0/5	
SESSION II	3.5	0/5	0/5	0/5	
	4.5	1./5	0/5	0/5	_
SESSION III	5.5	5/5	0/5	0/5	
	6.5	5/5	5/5	5/5	

The one-hour reaction in this patient appears as a papular formation. At 24 hours only the reactions at 6.5 J/cm<sup>2</sup> were still visible, as seen in Figure 57. No itching or discomfort was noted during the one-hour/24 hour period.



FIGURE 56 - PATIENT No. 11 - FIVE-MINUTES POST-EXPOSURE - SESSION II  $(3.5 \text{ J/cm}^2)$  Diffuse erythema noted, but no specific lesion in irradiated areas.

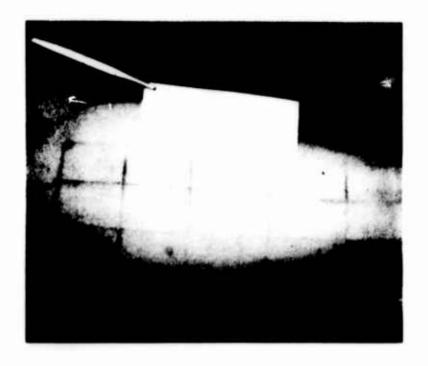


FIGURE 57 - PATIENT No. 11 - 24 HOURS POST-EXPOSURE - SESSION III

NOTE REACTIONS RETAINED AT 6.5 J/cm<sup>2</sup> IN ROW 3

## C. Argon laser series data analysis of Caucasian patients

Analysis of the data given in Tables XI, XII, XIII, XIV for patients No. 3, No 4, No. 5, and No. 6 was done by constructing a probability curve for each patient. This data is presented in Figure 58.

The data yielded a 50% probability for producing a minimal reaction (MRD  $_{50}$ ) ranging from 4.0  $\rm J/cm^2$  to 8.2  $\rm J/cm^2$ .

Comparison of the MRD values to the skin absorption data is given in Table XVII.

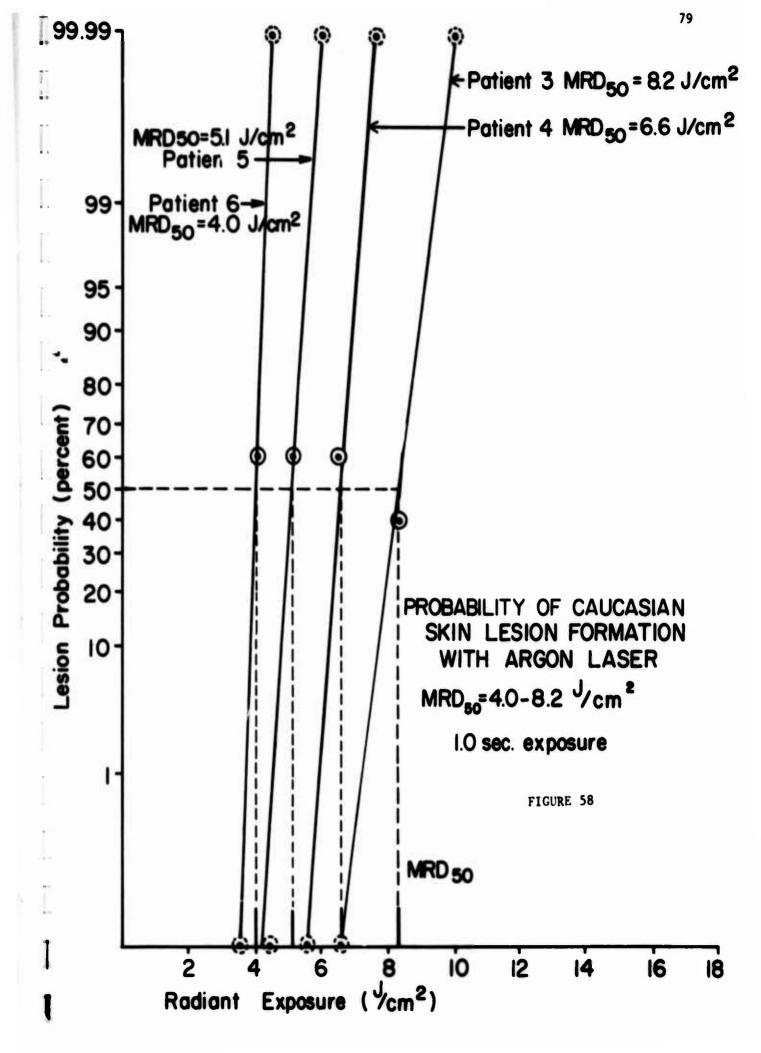


TABLE XVII
SUMMARY OF CAUCASIAN SKIN ABSORPTION DATA
ARGON LASER SERIES

PATIENT NUMBER	PERCENT ABSORPTION*	MRD <sub>50</sub> (J/cm <sup>2</sup> )	ABSORBED DOSE (J/cm <sup>2</sup> )
3	55	8.2	4.5
4	70	6.6	4.6
5	74	5.1	3.8
6	75	4.0	3.0

\*500 µm average wavelength was chosen for argon laser

It would appear then, that an average absorbed dose of about 4.0 J/cm<sup>2</sup> is the radiant exposure at which there is a 50% probability to produce a reaction by argon laser radiation in typical Caucasian skin for a 1.0 sec exposure over an area of 0.865 cm<sup>2</sup>.

## D. Argon laser series data analysis of Negro patients

Analysis of the data given in Tables XV and XVI for patients No. 10 and No. 11 was done by constructing a probability curve for both patients.

This data is presented in Figure 59.

The data yielded a 50% probability for producing a minimal reaction (MRD<sub>50</sub>) ranging from 4.5 J/cm<sup>2</sup> for darkly pigmented Negro skin (patient No. 10, reflectance: 9%) to 6.0 J/cm<sup>2</sup> for lightly pigmented Negro skin (patient No. 11, reflectance: 25%).

Comparison of the MRD values to the skin absorption data is given in Table XVIII

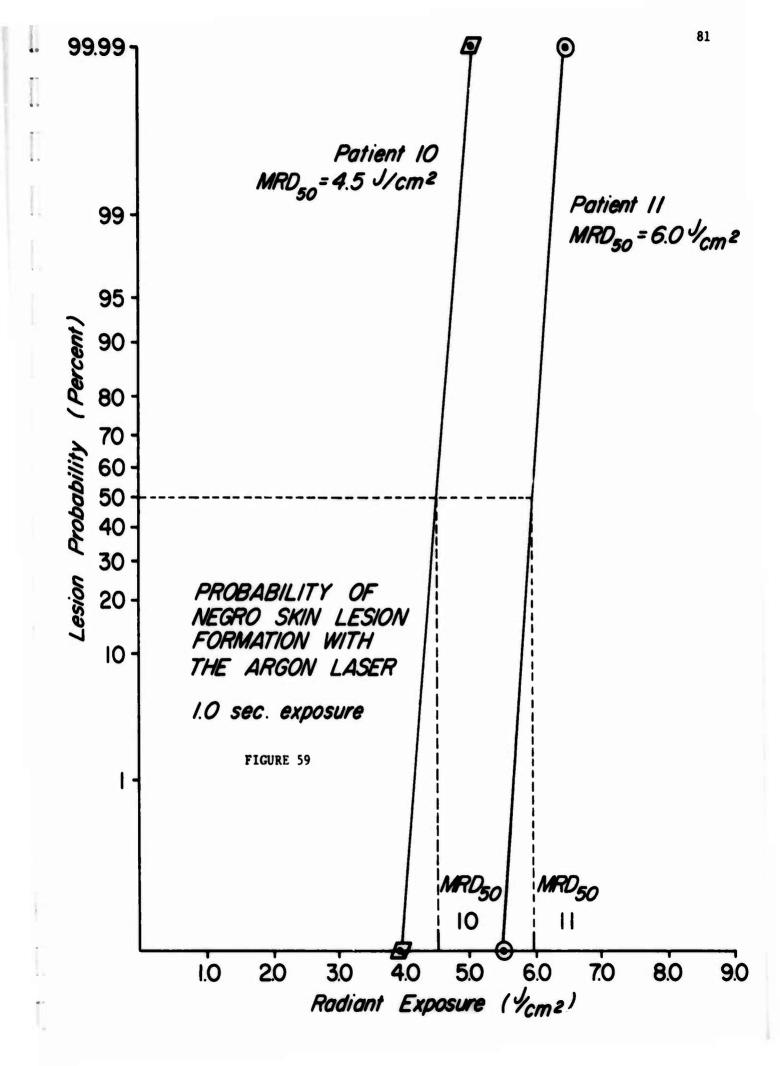


TABLE XVIII

SUMMARY OF NEGRO SKIN ABSORPTION DATA

ARGON LASER SERIES

PATIENT	PERCENT	MRD <sub>50</sub>	ABSORBED DOSE
NUMBER	ABSORPTION	(J/cm <sup>2</sup> )	$(J/cm^2)$
10	91	4.5	4.1
11	75	6.0	4.5

It would appear that an average absorbed dose of  $4.3 \text{ J/cm}^2$  is the radiant exposure at which there is a 50% probability to produce a minimal reaction by argon laser radiation in typical Negro skin for a 1.0 sec exposure over an area of  $0.865 \text{ cm}^2$ .

#### 3. CARBON DIOXIDE LASER SERIES

#### A. Exposure Data of all Patients

PATIENTS: NO. 12 (V.W), NO. 13 (L.G), NO. 14 (E.N), NO. 15 (S.F)

DATE OF TPEATMENT: All Patients - January 25, 1973

#### a. DESCRIPTION OF PATIENT NO. 12

The nation ( $W_*W$ ) is a twenty-three year old Negro male. The site of the irradiation was the flexor surface of the right forearm. The reflectance data for this patient is shown in (Appendix A - Figure 5)

## b. DESCRIPTION OF TREATMENT - PATIENT NO. 12

Five exposures were made at each of the levels of 0.6, 1.2, 1.7, 2.3, and 2.9  $J/cm^2$  for a total of 25 exposures.

An immediate visible reaction was noted only in the areas irradiated at a radiant exposure of 2.3 and 2.9 J/cm<sup>2</sup>. No itching or other sensations were noted.

## c. PESULTS - PATIENT NO. 12

Peactions were recorded in Table XIX and Figure 60.

POST-CO<sub>2</sub> LASER SKIN PEACTIONS

PATIENT NO. 12

PADIANT EXPOSIPE	PEACTION AT	PEACTION AT	PEACTION AT
(1/cm <sup>2</sup> )	5 MINUTES	1 HOUT	24 HOURS
0.6	n/5	0/5	0/5
1.2	0/5	0/5	0/5
1.7	0/5	0/5	0/5
2.3	2/5	0/5	0/5
2.9	5/5	4/5	3/5

The one-hour reaction in this patient were a series of small panular reactions. The patient at 24 hours indicated no itching or discomfort occurred during this period. Reactions could be observed in only three of the regions irradiated at 2.9 J/cm<sup>2</sup> and both reactions at the 2.3 J/cm<sup>2</sup> region had disappeared. (Figure 61)

## d. DESCRIPTION OF PATIENT NO. 13

The natient (IG) is a mixtu-seven year old Caucasion male.

The site of the irradiation was the flexor surface of the

left forearm. The patient had previously experienced repeated

ruby laser exposures (for testing purposes) on one very

small area of the forearm but this area was not part of the

skin surface used in this test. The reflectance data is

shown in Appendix A - Figure 5.

## e. DESCRIPTION OF TREATMENT - PATIENT NO. 13

Five exposures were made at each of the levels of 0.6, 1.2, 1.7, 2.3, and 2.9 J/cm<sup>2</sup> for a total of 25 exposures.

An immediate visible reaction was noted only in the areas irradiated at a radiant exposure of 2.3 and 2.9 J/cm<sup>2</sup>. No itching or other sensations were noted. (Figure 64)

#### f. RESULTS - PATIENT NO. 13

Reactions were recorded as given in Table XX and Figure 62.

TABLE XY

POST-CO<sub>2</sub>-LASER SKIN REACTIONS

#### PATIENT # 13

PADIANT EXPOSUPE	REACTION AT	PEACTION AT	REACTION AT
(1/cm <sup>2</sup> )	5 MINUTES	1 HOUR	24 HOURS
0.6	0/5	0/5	0/5
1.2	0/5	0/5	0/5
1.7	0/5	0/5	0/5
2.3	2/5	0/5	0/5
2.9	5/5	4/5	3/5

The one-hour reaction of this patient was a diffuse red ervthema.

The patient at 24 hours indicated that no itching or other discomfort had occurred throughout the period. The reaction in the areas irradiated at 2.3 J/cm<sup>2</sup>, had completely disappeared. Two of the five reactions in the areas irradiated at 2.9 J/cm<sup>2</sup> had disappeared.

This natient (LG) had previously shown indications to be photosensitive to ruby laser irradiation. In this case, reactions did not subside at 24 hours and the presence of severe itching, papules and blisters following the ruby laser irradiation had indicated a more severe reaction than is normally encountered. None of this was observed following the CO<sub>2</sub> laser irradiation.

#### g. DESCRIPTION OF PATIENT # 14

The patient (E.N.) is a 51 year old negro male. The site of the test exposures was the flexor surface of the right forearm. The reflectance data is given in Figure 19.

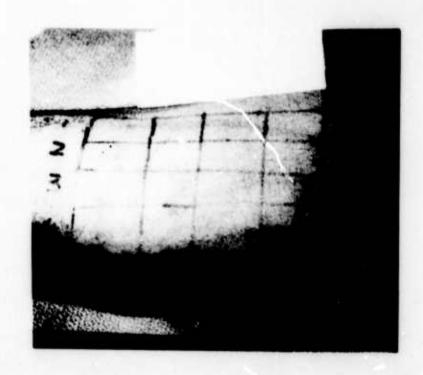


FIGURE 60 - PATIENT No. 12 - ONE-HOUR POST-EXPOSURE

NOTE SMALL REACTIONS IN ROW 5 (2.9 J/cm<sup>2</sup>)

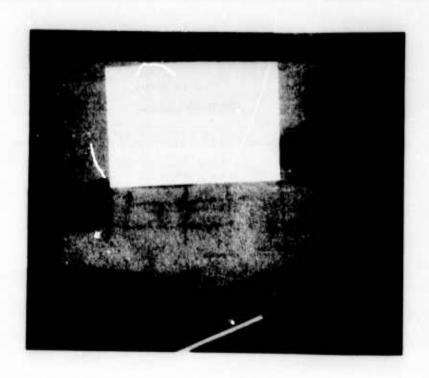


FIGURE 61 - PATIENT No. 12 - 24 HOURS POST-EXPOSURE. SMALL
PAPULAR REACTIONS ARE STILL OBSERVED AT THIS TIME.

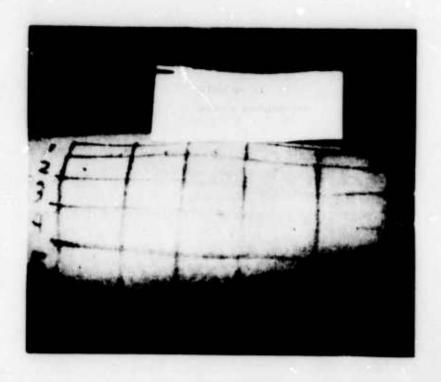


FIGURE 62 - PATIENT No. 13 - FIVE-MINUTES POST-EXPOSURE



FIGURE 63 - PATIENT No. 13 - ONE-HOUR POST-EXPOSURE

## h. DESCRIPTIONS OF TEST EXPOSURES - PATIENT No. 14

Five exposures were made at each of the levels of 0.6, 1.2, 1.7, 2.3 and 2.9  $1/\text{cm}^2$  for a total of 25 exposures.

No immediate sensations were noted by the patient. Three of the areas exposed at 2.3 1/cm<sup>2</sup> showed a definite red ervthema at 5 minutes post-irradiation which disappeared at the one-hour post-treatment examination. (Figure 64)

## 1. PESILTS - PATIENT No. 14

Reactions were recorded as given in Table XXI

TABLE YXI
POST-CO<sub>2</sub>-LASER SKIN REACTIONS

PATIENT N	n. 14	
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RADIANT EXPOSURE	REACTION AT	REACTION AT	REACTION AT
(J/cm <sup>2</sup> )	5 YINUTES	1 HOUR	24 HOURS
0.6	0/5	0/5	0/5
1.2	0/5	0/5	0/5
1.7	0/5	0/5	0/5
2.3	3/5	0/5	0/5
2.9	3/5	4/5	3/5

The one-hour reaction in this patient was uniform erythema.

At 24 hours all but three of the reactions at 2.9 J/cm<sup>2</sup> had completely disappeared. No itching or discomfort was noted during the one-hour/24 hour period.



FIGURE 64 PATIENT NO. 14 - FIVE MINUTES POST- EXPOSURE
TEMPLATE DENOTES REGION OF DIFFUSE ERYTHEMA

## j. DESCRIPTION OF PATIENT NO. 15

The nation (S.F.) is a thirty-two year old Caucasian male. The site of the test exposures was the flexor surface of the right forearm. The reflectance data is presented in Appendix A = Figure 5.

## k. DESCRIPTION OF TREATMENT - PATIENT NO. 15

Tive exposures were made at each of the levels of 0.6, 1.2, 1.7, 2.3, and 2.9 J/cm<sup>2</sup> for a total of 25 exposures.

Immediately following exposure the patient experienced nearsyncone (fainting) and the diffuse erythema which was present
in the region completely faded. The near syncopal episode was
associated with anxiety of the treatment and was not related

directly to an effect of the laser impact.

## 1. RESULTS - PATIENT NO. 15

Reactions were recorded as given in Table XXII.

TABLE XXII

# POST-CO2-LASER SKIN REACTIONS

#### PATIENT NO. 15

RADIANT	EXPOSUPE	REACTION AT	PEACTION AT	PEACTION AT
(J/	cm <sup>2</sup> )	5 MINITES	1 HOUR	24 HOURS
0.6		0/5	0/5	0/5
1.2		0/5	0/5	0/5
1.7		0/5	0/5	0/5
2.3		3/5	0/5	0/5
2.9		5/5	4/5	1/5

The one-hour reaction in this patient was a mild erythema.

The remaining reaction at 24 hours showed a small blister.

(No 24 hour photograph available due to camera malfunction).

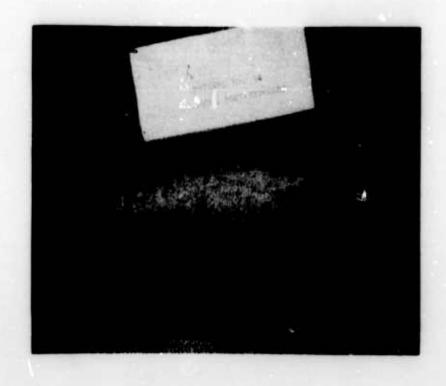


FIGURE 65 - PATIENT No. 14 - 24 HOURS POST-EXPOSURE. MILD LESIONS IN ROW 5 (2.9 J/cm<sup>2</sup>) BARELY VISIBLE.

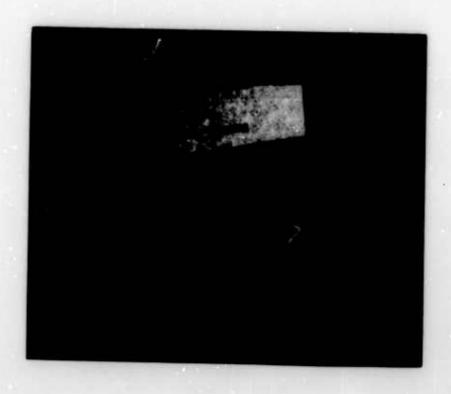


FIGURE 66 - PATIENT NO. 15 - ONE-HOUR POST-EXPOSURE

CARBON DIOXIDE SERIES - DATA ANALYSIS OF ALL PATIENTS

A summary of all the data recorded for all exposures to all patients is given in Table XXIII. This includes the reaction analysis at five-minutes, one hour, and 24 hours. This data is a synonsis of the data contained in Tables XIX, XX, XXI, and XXIII.

TABLE XXIII

#### SUPCHARY OF ALL SKIN EXPOSURE DATA

#### CARBON DIOXIDE LASER SERIES

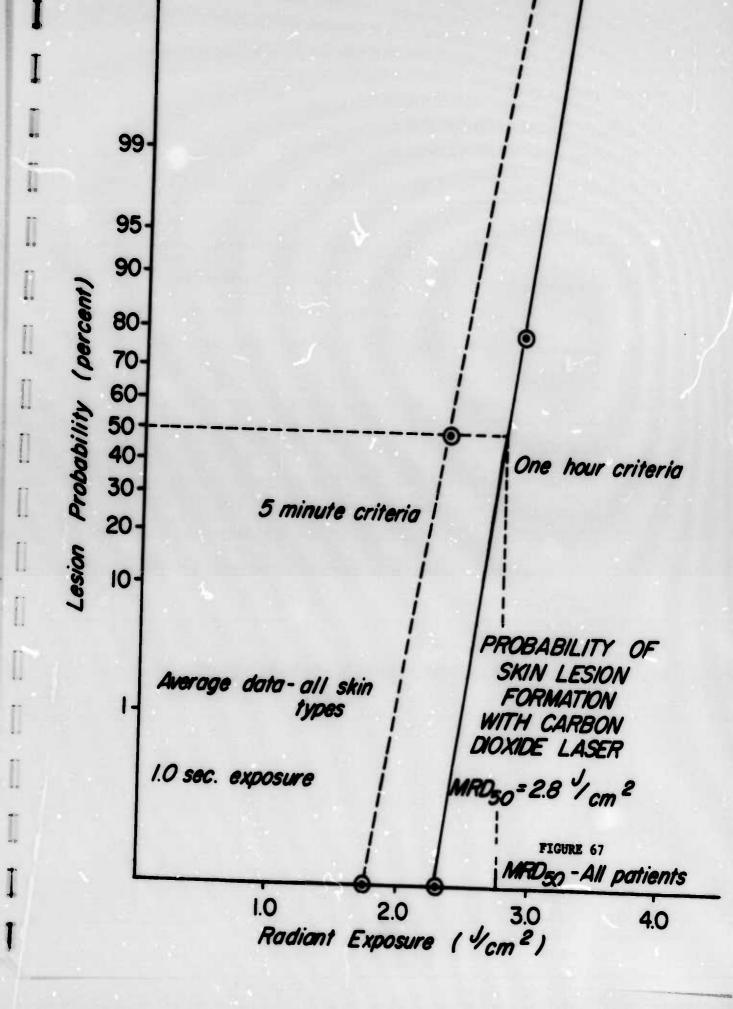
NUMBER OF	RADIANT EXPOSURES	VISIBLE REACTIONS		PRESENT
EXPOSITES	(1/cm <sup>2</sup> )	5 MINUTES	1 Hour	24 HOURS
20	0.6	0	0	0
20	1.2	0	U	0
20	1.7	0	0	0
20	2.3	50%	0	0
20	2.9	100%	80%	50%

The exposures given in this series were pre-selected to hopefully yield the minimum possibility of any longterm reaction (depigmentation, scarring, etc.). The reaction observed at 2.3 and 2.9 J/cm<sup>2</sup> on both the Caucasian and Negro skin was a diffuse erythema which, for exposures at 2.3 J/cm<sup>2</sup> faded within one-hour. A mild erythema persisted in one-half of the cases up to 24 hours for an exposure of 2.9 J/cm<sup>2</sup>.

Probability curves were constructed to determine the radiant exposure at which there is a 50% probability for a minimal reaction (MRD<sub>50</sub>) for both the five-minute and one-hour criteria data points. (Figure 67). The data yielded MRD<sub>50</sub>=2.8 J/cm<sup>2</sup> for the one-hour-criteria.

It is of note that the one-hour criteria data was later confirmed during subsequent tests on another Caucasian patient during tests to determine the construction of the tissues at five-minutes following irradiation by cong laser. These tests indicated that the temperature rise at five minutes was less than 2°C.

Since the device used for the reflectance tests performed on these patients did not extend up to the 10,600 nm range of the  $CO_2$  laser wavelength, specific data analysis of absorbed dose could not be done. It has been reported in the literature by Fine, et al<sup>(8)</sup> that up to 95% of incident  $CO_2$  laser irradiation will be absorbed by the skin. This would yield an absorbed dose at the MRD<sub>50</sub> level for all skin types of 2.7  $J/cm^2$ .



#### 4. NEODYMIUM-YAG LASER SERIES

#### A. Exposure Data of Negro Patients

PATIENTS: No. 17 (H.C.), No. 18 (I.H.)

DATE OF TREATMENT: May 18, 1973

a. DESCRIPTION OF PATIENT No. 17

The nation is a 21 year old Negro male. The site of the irradiation was the flexor surface of the right forearm. Reference to his reflectance data (Appendix A - Figure 6) and the data of Kuppenheim would indicate that up to 55% of the incident YAG laser would be absorbed by the skin.

#### b. DESCRIPTION OF TREATMENT OF PATIENT No. 17

Five exposures were made at each of the levels of 20, 30, 40, and  $50 \text{ J/cm}^2$  for a total of 20 exposures.

An immediate visible reaction was noted in the areas irradiated at a radiant exposure of 30 to 50  $\rm J/cm^2$ . No itching or other sensations were noted. The irradiation was extremely painful to this subject, especially at the higher level of 50  $\rm J/cm^2$ .

#### c. RESULTS - PATIENT No. 17

Reactions were recorded as given in Table XXIV.

TABLE XXIV

POST-YAG-LASER SKIN REACTIONS

PATIENT No. 17

RADIANT	REACTION AT	REACTION AT	REACTION AT
EXPOSURE (J/cm <sup>2</sup> )	FIVE-MINUTES	ONE-HOUR	24-48 HOURS
20	0/5	0/5	0/5
30	1/5	0/5	0/5
40	5/5	1/5	0/5
50	4/5	4/5	2/5

The one-hour reaction of this patient was the formation of small papules. The patient at 24-48 hours indicated that absolutely no itching occurred in the arm during this period. Two of the four papular areas still contained small papules and faint erythema. These areas measured approximately 0.5 cm diameter.



FIGURE 68 - PATIENT No. 17 - ONE-HOUR POST-EXPOSURE. AREAS OF SMALL PAPULE FORMATION ARE DESIGNATED BETWEEN LINES DRAWN ON SKIN.

## d. DESCRIPTION OF PATIENT No. 18

The patient (I.H.) is a thirty year old Negro male who had previously been a subject for ruby and argon laser testing for MPE levels. The site of the test exposures was the flexor surface of the left forearm.

Reference to his reflectance data (Appendix A - Figure 6) and the Kuppenheim data would indicate up to 55% of the incident TAG laser would be absorbed by the skin.

# e. DESCRIPTION OF TREATMENT OF PATIENT No. 18

Five exposures were made at each of the levels of 20, 30, 40, 45, 50 60 and 70  $J/cm^2$  for a total of 35 exposures. The irradiation was moderately painful to the subject.

Areas exposed at and above 60 J/cm<sup>2</sup> showed a panular formation and some erythemia at five-minutes post-irradiation which persisted through the one-hour post-treatment examination.

#### f. RESULTS - PATIENT No. 18

Peactions were recorded as given in Table XXV.

TABLE XXV

#### POST-YAC LASER SKIN REACTIONS

#### PATIENT No. 18

PADIANT EXPOSURE (.1/cm <sup>2</sup> )	REACTION AT FIVE-MINITES	PEACTION AT ONE-HOUR	REACTION AT 24-48 HOURS
20	0/5	0/5	0/5
30	0/5	0/5	1/5
40	1/5	0/5	0/5
45	3/5	0/5	0/5
50	3/5	0/5	1/5
60	2/5	2/5	1/5
70	5/5	5/5	5/5

The one-hour reaction in this natient were small papules and diffuse ervthema. At 24-48 hours, reactions were still observed in all five areas irradiated at  $70 \text{ J/cm}^2$ . One "reaction" appeared at  $30 \text{ J/cm}^2$ , but was questioned as artifact.

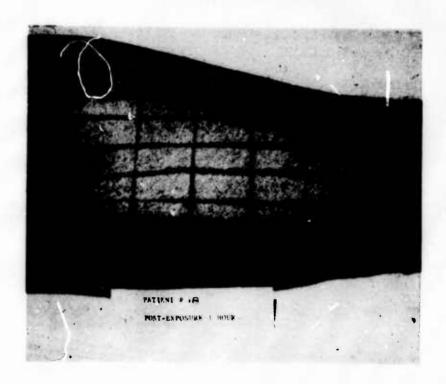


FIGURE 69 - PATIENT No. 18 - REACTIONS AT ONE-HOUR POST-EXPOSURE

## B. Exposure data - Caucasian Patients

PATIENTS No. 19 (R.D.), No. 20 (R.J.R.)

DATE OF TREATMENT: May 18, 1973

#### a. DESCRIPTION OF PATIENT No. 19

The patient (R.D.) is a 26 year old Caucasian male. The site of the test exposures was the flexor surface of the right forearm.

Reference to his reflectance data and the Kuppenheim data would indicate that up to 50% of the incident YAG laser beam would be absorbed by the tissues. (Appendix A - Figure 6)

# b. DESCRIPTION OF TREATMENT OF PATIENT No. 19

Five exposures were made at each of the levels of 30, 40, 45, 50 and 60  $J/cm^2$  for a total of 25 exposures. The irradiations at 50 and 60  $J/cm^2$  were very painful to the patient. Immediate reactions

were observed at all but the 30 J/cm<sup>2</sup> radiant exposure level.

## c. RESULTS - PATIENT No. 19

Reactions were recorded as given in Table XXVI and Figure 70.

TABLE XXVI

#### POST-YAG LASER SKIN REACTIONS

#### PATIENT No. 19

RADIANT EXPOSURE (J/cm <sup>2</sup> )	REACTION AT FIVE-MINUTES	REACTION AT ONE-HOUR	REACTION AT 24-48 HOURS
30	0/5	0/5	0/5
40	(5/5)*	(3/5)*	0/5
45	4/5	2/5	0/5
50	3/5	3/5	0/5
60	5/5	5/5	5/5

\*Data not included in 'MRD<sub>50</sub> determination. This area of arm more deeply pigmented than other areas irradiated.

The one-hour reaction in this patient was a papular reaction in the irradiated areas. The papular reaction at  $60 \text{ J/cm}^2$  observed at 24-48 hour period is shown in Figure 70.

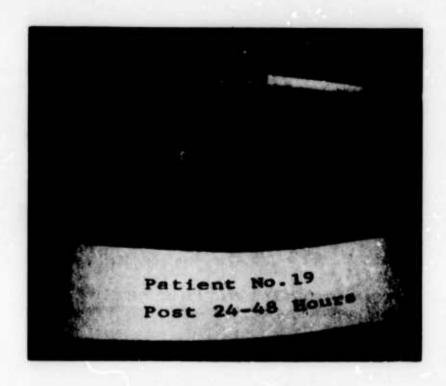


FIGURE 70 - PATIENT No. 20 - 24-48 HOUPS POST-EXPOSURE (YAG)
SHOWING PAPULAR REACTION AT 60 J/cm<sup>2</sup>

# d. DESCRIPTION OF PATIENT No. 20

The patient (RJR) is a 36 year old Caucasian male. The site of the test exposures was the flexor surface of the right forearm.

Reference to his reflectance data (Appendix A - Figure 6) and the data of Kuppenheim would indicate that up to 40% of the incident radiation will be absorbed by the skin.

# e. DESCRIPTION OF TREATMENT OF PATIENT No. 20

Five exposures were made at each of the levels of 40, 50, 60, 70, and 80 J/cm<sup>2</sup> for a total of 25 exposures.

# f. RESULTS - PATIENT No. 20

Reactions were recorded as given in Table XXVII.

TABLE XXVII

#### POST-YAG-LASER SKIN REACTIONS

#### PATIENT No. 20

RADIANT EXPOSURE (J/cm <sup>2</sup> )	REACTION AT FIVE MINUTES	REACTION AT ONE-HOUR	REACTION AT 24-48 HOURS
40	1/5	0/5	0/5
50	0/5	0/5	0/5
60	0/5	0/5	0/5
70	0/5	0/5	0/5
80	4/5	4/5	1/5

The one-hour reaction in this patient was a series of raised hemorrhagic spots and a mild short-term (15 minute) diffuse erythema.

The examination at 24-48 hours showed only one reaction at the 80 J/cm<sup>2</sup> level. The entire region of the arm was, however, extremely "mensitive" during this period, (similar to the sensation following a mild sunburn). All such sensation ceased at 48 hours.

# C. NEODYMIUM-YAG LASER SERIES - DATA ANALYSIS OF CAUCASIAN PATIENTS

Analysis of the data given in Tables XXVI and XXVII for nationts No. 19 and No. 20 was done by constructing a probability curve for both patients. This data is presented in Figure 71.

The data yielded a 50% probability for producing a minimal reaction (MRD<sub>50</sub>) ranging from 49  $J/cm^2$  for a darkly pigmented (sun-tanned) Caucasian (patient No. 19) to 78  $J/cm^2$  (patient No. 20) for a light-

pigmented (fair-complected) Caucasian. Direct comparison of the MRD values to the skin absorption data was not possible due to the visible wavelength range limitations of the device used to obtain the skin reflectance data. As discussed in Section II-B, one can estimate from the data of Kuppenheim (7) that darkly pigmented Caucasian skin will absorb 50% and lightly pigmented Caucasians will absorb 40% at the 1,060 nm wavelength of the YAG laser. Thus, one can estimate the absorbed dose at the MRD<sub>50</sub> level as given in Table XXVIII.

TABLE XXVIII
SUMMARY OF CAUCASIAN SKIN ABSORPTION DATA

Nd-YAG LASER SERIES

PATIENT	PERCENT	MRD <sub>50</sub>	ABSORBED DOSE
NUMBER	ABSORPTION* (1,060 nm)	(J/cm <sup>2</sup> )	(J/cm <sup>2</sup> )
19	50	48	24
20	40	78	31

\*Based on data of Kuppenheim

Hence, on the average, an absorbed dose of approximately  $28 \text{ J/cm}^2$  is the absorbed radiant exposure at which there is a 50% probability to produce a minimal reaction with Nd-YAG laser radiation in Caucasian skin for a 1.0 sec exposure over an area of  $0.865 \text{ cm}^2$ .

D. <u>NEODYMIUM-YAG LASER SERIES - DATA ANALYSIS OF NEGRO PATIENTS</u>

Analysis of the data given in Tables XXIV and XXV for patients No. 17

and No. 18 was done by constructing a probability curve for both patients.

This data is presented in Figure 71.

The data yielded a 50% probability for producing a minimal reaction (MRD $_{50}$ ) ranging from 46 J/cm $^2$  (patient No. 17) to 60 J/cm $^2$  (patient No. 18). Direct comparison of the MRD values to the skin absorption data was not

possible due to the visible wavelength-range limitation of the device used to obtain such data. As discussed in Section II-B, one can estimate from the data of Kuppenheim that dark Negro skin will absorb about 55% at the 1,060 nm wavelength of the Nd-YAG laser. Thus, using reflectance data of the patients' skin obtained at 700 nm as a guide, one can estimate the absorbed dose at the MRD<sub>50</sub> level as given in Table XXIX.

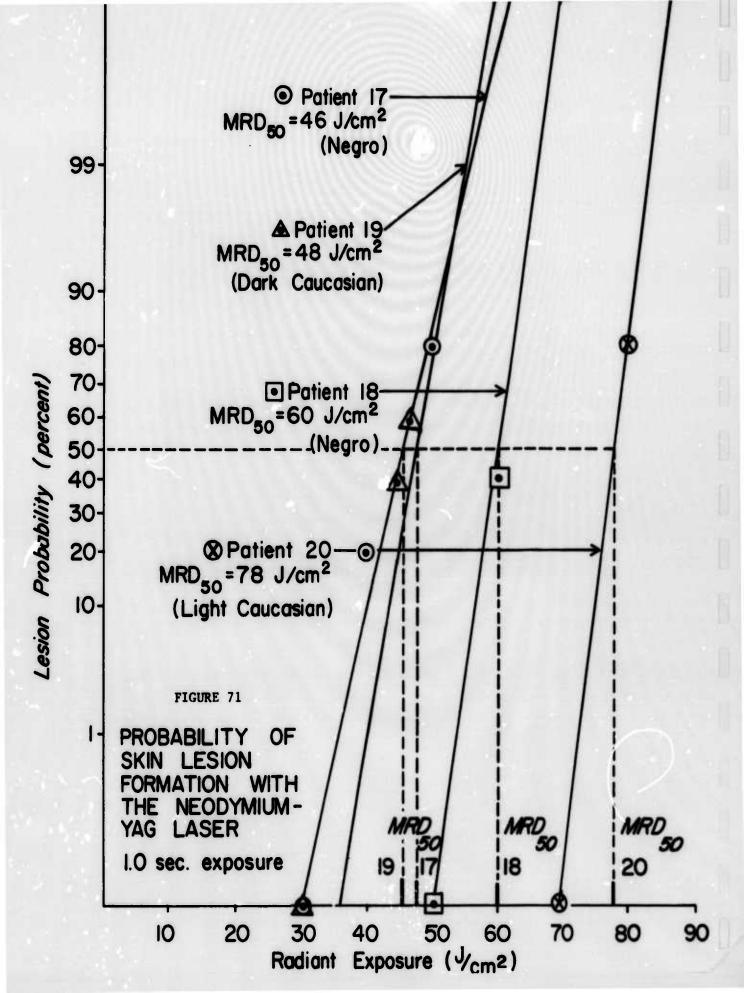
# TABLE XXIX SUMMARY OF NEGRO SKIN ABSORPTION DATA

#### Nd-YAG LASER SERIES

PATIENT	PERCENT	MRD <sub>50</sub>	ABSORBED DOSE
NUMBER	ABSORPTION*	$(J/cm^2)$	$(J/cm^2)$
17	55	46	25
18	55	60	33

\*Based on the data of Kuppenheim

Hence, on the average, an absorbed dose of about 29  $J/cm^2$  is the radiant exposure at which there is a 50% probability to produce a minimal reaction with the Nd-YAG laser radiation in Negro skin for a 1.0 sec exposure over an area of 0.865 cm<sup>2</sup>.



## 5. Q-SWITCHED RUBY LASER SERIES

#### A. Exposure Data - Caucasian Patients, Q-Switched Ruby Laser

PATIENTS: No. 21 (R.F.), No. 22 (G.D.)

DATE OF TREATMENT: December 13, 1973

#### a. DESCRIPTION OF PATIENT No. 21

The patient (R.F.) is a 24 year old Caucasian male. The site of the irridiation was the flexor surface of the right forearm. Reference to his reflectance data (Appendix A - Figure 7) indicates that 33% of the incident ruby laser radiation will be absorbed by the skin of this patient.

## b. DESCRIPTION OF TREATMENT - PATIENT No. 21

Five exposures were made at each of the levels of 0.13, 0.22, (2 rows) 0.54 and 1.28  $J/cm^2$  for a total of 25 exposures.

A visible erythema was observed at five-minutes post-irradiation at the levels of 0.54 and 1.28 J/cm<sup>2</sup>. At these radiant exposures, small puffs of smoke were released from the skin at the moment of irradiation. The patient indicated that he "felt" these doses, but experienced virtually no sensation of irradiation at the lower doses. No itching or other sensations were noted. The irradiations were described by the subject as not painful.

## c. RESULTS - Patient No. 21

Reactions were recorded as given in Table XXX and Figure 72.

TABLE XXX

#### POST-Q-SWITCHED RUBY LASER SKIN REACTIONS

PATIENT No. 21 - CAUCASIAN SKIN

RADIANT EXPOSURE  (J/cm <sup>2</sup> )	REACTION AT FIVE-MINUTES	REACTION AT ONE-HOUR	REACTION AT 24 HOURS
0.13	0/5	0/5	0/5
0.22	2/5	1/5	0/5
0.22	3/5	1/5	0/5
0.54	5/5	5/5	5/5
1.28	5/5	5/5	5/5

The reaction of this patient at one-hour was a definite red erythema. At 24 hours, all reactions at radiant exposure levels below  $0.54 \text{ J/cm}^2$  had faded, and the intensity of the reactions at 0.54 and  $1.28 \text{ J/cm}^2$  had also significantly resided.

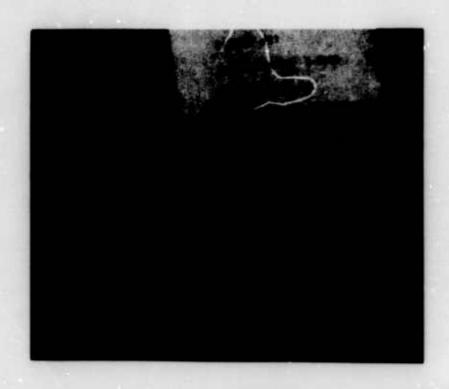


FIGURE 72 - PATIENT No. 21 - ONE-HOUR POST-EXPOSURE. DEFINITE REACTION
OBSERVED IN ROW 1 (0.54 J/cm<sup>2</sup>) AND ROW 5 (1.28 J/cm<sup>2</sup>)

#### d. DESCRIPTION OF PATIENT No. 22

The patient (G.D.) is a twenty-four year old Caucasian male. The site of the test exposures was the flexor surface of the right forearm.

Reference to his reflectance data (Appendix A - Figure 7) indicates that 44% of the incident ruby laser radiation will be absorbed by the skin.

#### e. DESCRIPTION OF TREATMENT - PATIENT No. 22

Five exposures were made at each of the levels of 0.13, 0.26, 0.37, 0.54, and 1.28  $J/cm^2$  for a total of 25 exposures.

A visible red erythema was observed at five-minutes post-irradiation at all radiant exposure levels. The erythema at all but the 0.13 J/cm<sup>2</sup> persisted throughout one-hour post-irradiation examination. The patient also described an itchiness in these areas which started approximately 20 minutes post-exposure and had completely subsided at the 24 hour examination.

Small red papules were noted in the area of irradiation at the 1.28 J/cm<sup>2</sup> level.

## f. RESULTS - PATIENT No. 22

Reactions are recorded as given in Table XXXI and Figure 73.

TABLE XXXI

POST-Q-SWITCHED RUBY LASER SKIN REACTIONS

PATIENT No. 22 - CAUCASIAN SKIN

RADIANT EXPOSURE (J/cm <sup>2</sup> )	REACTION AT FIVE-MINUTES	REACTION AT ONE-HOUR	REACTION AT 24 HOURS
0.13	2/5	0/5	0/5
0.26	1/5	3/5	0/5
0.37	5/5	5/5	0/5
0.54	5/5	5/5	5/5
1.28	5/5	5/5	5/5

The one-hour reaction of this patient was a definite red erythema and formation of small red papules at the higher exposure levels. At 24 hours, all reactions at radiant exposure levels below  $0.54 \text{ J/cm}^2$  had also significantly receded.



FIGURE 73 - PATIENT No. 22 - ONE-HOUR POST-EXPOSURE. DEFINITE LESIONS OBSERVED IN ROW 3 (0.54  $\rm J/cm^2$ ) AND ROW 5 (1.28  $\rm J/cm^2$ ). MILDER LESIONS IN ROW 2 (0.37  $\rm J/cm^2$ ) BARELY OBSERVABLE.

## B. Exposure Data - Negro Patients, Q-Switched Ruby Laser

PATIENTS: No. 23 (S.H.), No. 24 (J.H.)

DATE OF TREATMENT: December 13, 1973

## a. DESCRIPTION OF PATIENT No. 23

The patient (S.H.) is a forty-three year old Negro male. The site of irradiation was the flexor surface of the right forearm. This ratient had previously served as a volunteer for ruby laser testing (patient No. 16). At that time both right and left forearms were used for test sites. No skin reactions were recorded at that time for any of the exposures of the right forearm. (Sessions I and II - See Table VIII) The exposures given during this session with the Q-switched ruby laser were not placed in an area on his skin where there was any observable lesion or effect from a prior laser exposure or trauma of any other nature. Reference to his reflectance data (Appendix A - Figure 7) indicates that 76% of the incident ruby laser radiation will be absorbed by the skin.

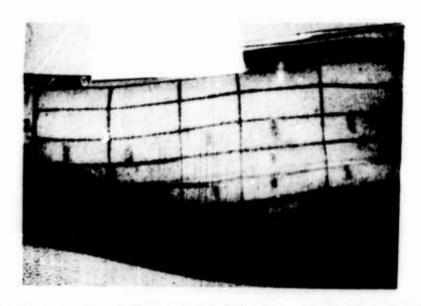


FIGURE 74 - PATIENT No. 23 - ONE-HOUR POST-EXPOSURE. DEFINITE LESIONS OBSERVABLE IN ROW 3 (0.54  $J/cm^2$ ) AND ROW 5 (0.37  $J/cm^2$ ). NOTE MILDER LESIONS IN ROW 4 (0.26  $J/cm^2$ ).

## b. DESCRIPTION OF TREATMENT - PATIENT No. 23

Five exposures were made at each of the levels of 0.13, 0.22, 0.26, 0.37, 0.54  $J/cm^2$  for a total of 25 exposures.

A visible erythema with a tiny ashen-white center was observed as the minimal reaction at the levels of 0.37 and  $0.54 \text{ J/cm}^2$ . The ashen-white color had disappeared 12 hours post-exposure in this patient.

## c. RESULTS - PATIENT No. 23

Reactions are recorded as given in Table XXXII and Figure 74.

TABLE XXXII

POST-Q-SWITCHED RUBY LASER SKIN REACTIONS

PATIENT No. 23 - NEGRO SKIN

RADIANT EXPOSURE	REACTION AT	REACTION AT	REACTION AT
(J/cm <sup>2</sup> )	FIVE-MINUTES	ONE-HOUR	24 HOURS
0.13	0/5	0/5	0/5
0.22	0/5	0/5	0/5
0.26	1/5	4/5	4/5
0.37	4/5	5/5	5/5
0.54	5/3	5/5	5/5

The one-hour reaction of this patient was an erythema and white-ashen color that appeared instanteneously following irradiation. At 24 hours, the white-ashen discoloration had disappeared, but the erythema was still visible in those areas exposed at 0.26 J/cm<sup>2</sup> or higher that had been visible at the one-hour examination.

#### d. DESCRIPTION OF PATIENT No. 24

The patient (J.H.) is a 43 year old Negro male. The site of the test exposures was the flexor surface of the right forearm. Reference to his reflectance data (Appendix A - Figure 7) indicates that 59% of the incident ruby laser radiation will be absorbed by the skin.



FIGURE 75 - PATIENT No. 24 - ONE-HOUR POST-EXPOSURE

NOTE DEFINITE LESIONS IN ROW 3 (0.54 J/cm<sup>2</sup>).

ASHEN-WHITE CHAR IN A LINEAR ARRANGEMENT IS CLEARLY

EVIDENT.

#### e. DESCRIPTION OF TREATMENT - PATIENT No. 24

Five exposures were made at each of the levels of 0.13, 0.22, and  $0.54 \text{ J/cm}^2$  for a total of 15 exposures. Additional exposures at higher levels were not required for this patient.

An erythema with a definite ashen-white center was the minimal reaction observed for this patient. The ashen center was instantaneously observed following irradiation at the  $0.54~\mathrm{J/cm}^2$  level. One very small papule reaction was seen at  $0.22~\mathrm{J/cm}^2$ .

#### f. RESULTS - PATIENT No. 24

Reactions are recorded as given in Table XXXIII and Figure 75.

TABLE XXXIII

POST-Q-SWTICHED RUBY LASER SKIN REACTIONS

#### PATIENT No. 24 - NEGRO SKIN

RADIANT EXPOSURE (J/cm <sup>2</sup> )	REACTION AT FIVE-MINUTES	REACTION AT ONE-HOUR	REACTION AT 24 HOURS
0.13	0/5	0/5	0/5
0.22	1/5	1/5	0/5
0.54	5/5	5/5	5/5

The one-hour skin reaction of this patient was an erythema and ashen-white color that was visible instantaneously following irradiation. At 24 hours, the ashen-white skin discoloration had disappeared, but erythema was still visible in the areas exposed at  $0.54 \text{ J/cm}^2$ .

#### C. Q-SWITCHED RUBY LASER - DATA ANALYSIS OF ALL PATIENTS

Analysis of the data given in Tables XXX, XXXI, XXXII, and XXXIII for patients No. 21, No. 22, No. 23, and No. 24 was done by constructing probability curves from the data for each patient exposed to the Ruby-Q-Switched laser. The data yielded a 50% probability for producing a

minimal reaction ranging from 0.25  $J/cm^2$  to 0.34 .7/ $cm^2$  as shown in Figure 76.

Comparison of the MRD values to the skin absorption data is given in Table XXXIV.

TABLE XXXIV
SUMMARY OF SKIN ABSORPTION DATA

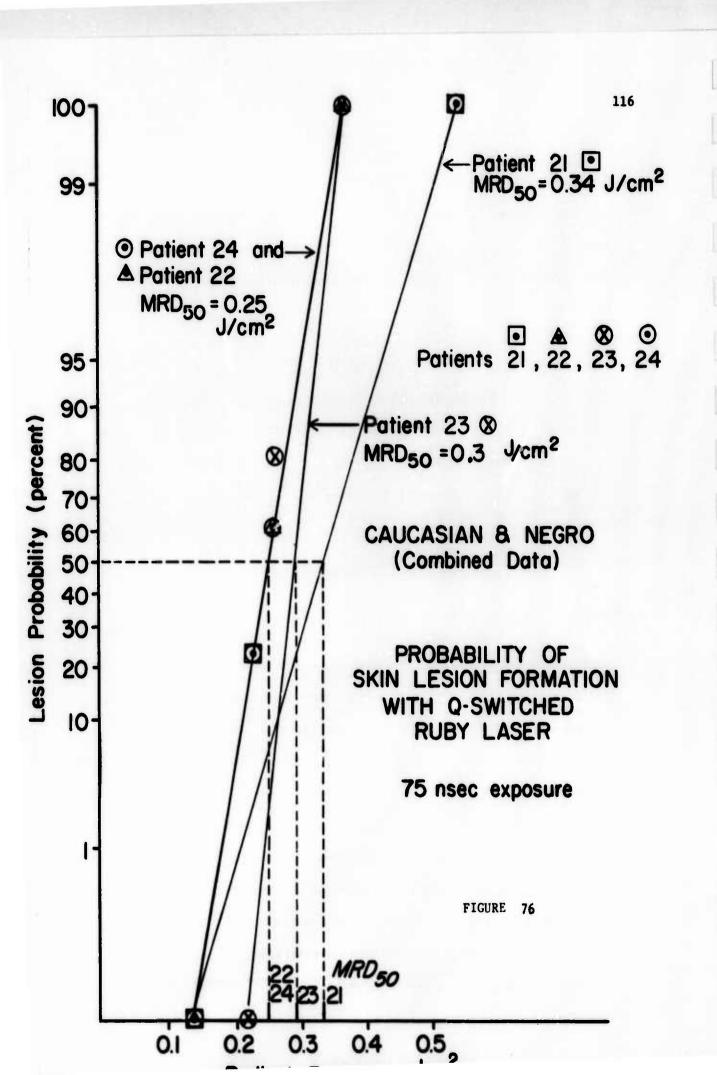
Q-SWITCHED-RUBY-LASER SERIES

PATIENT	RACE	PERCENT	MRD <sub>50</sub>	ABSORBED DOSE
NUMBER		ABSORPTION	$(J/cm^2)$	$(J/cm^2)$
21	C	33	0.34	0.11
22	C	44	0.25	0.11
23	N	76	0.30	0.23
24	N	59	0.25	0.15

Hence, it would appear that an average dose of approximately  $0.11 \text{ J/cm}^2$  for Caucasian skin and  $0.19 \text{ J/cm}^2$  for Negro skin are the absorbed radiant exposures at which there is a 50% probability to produce a minimal reaction with the Q-switched-ruby-laser operating at 75 nsec over an area of  $0.865 \text{ cm}^2$ .

This result indicates that the darker pigmented Negro skin requires nearly twice the absorbed radiant exposure than the Caucasian skin. This result can, perhaps, be explained by considering the fact that the criteria for establishing the MRD in Caucasian skin was presence of erythema, papules, etc. at the five-minute and one-hour examinations.

The minimal visible skin reaction criteria imposed by the immediate reaction of the Q-switched radiation on Negro skin was the formation of an



ashen-white "char" which usually persisted one-hour (but seldom 24 hours). Erythema on Negro skin usually appeared as a secondary response in these areas - especially at the one-hour examination. Consequently, the heavy pigment in the Negro skin appears to serve as a "barrier" to erythema production at lower radiant exposure levels. Apparently, the absorption in Negro skin is primarily concentrated in the layer of pigmented cells. As a result, a higher absorbed radiant exposure is required to cause a visible reaction which first occurs in the form of an immediate ashen-white char. Hence, the vascular bed under the pigmented cells (which contributes to the erythema observed in the Caucasian skin) is not as extensively disturbed by transmitted Q-switched-ruby-laser radiation in Negro skin at the lower radiant exposure levels (0.11 J/cm<sup>2</sup>) where erythema reactions are produced in Caucasian skin.

#### 6. Q-SWITCHED NEODYMIUM LASER SERIES

A. Exposure Data - Caucasian Patients, Q-Switched Nd. Laser

PATIENTS: No. 25 (E.P.), No. 26 (R.F.)

DATE OF TREATMENT: December 14, 1973

a. DESCRIPTION OF PATIENT No. 25

The patient (E.P.) is a twenty-six year old Caucasian male. The site of irradiation was the flexor surface of the right forearm. The absorption was estimated from Table I to be 47%, using the reflectance data in Appendix A - Figure 8.

b. DESCRIPTION OF TREATMENT - PATIENT No. 25

Five exposures were made at each of the levels of 2.60, 3.7, 4.8 and 7.1 J/cm<sup>2</sup> for a total of 20 exposures. Four exposures were made at a level of 8.8 J/cm<sup>2</sup> to yield a grand total of 24 exposures. Reactions were observed instantaneously at all levels except the lowest of 2.6 J/cm<sup>2</sup>. At 7.11 J/cm<sup>2</sup>, the irradiation seemed to "clean the skin" and produced a tiny papule. Definite papules were produced at five minutes at 8.8 J/cm<sup>2</sup>.

c. RESULTS - PATIENT No. 25

Reactions are recorded as given in Table XXXV and Figure 77.

TABLE XXXV

#### Q-SWITCHED-NEODYMIUM LASER SKIN REACTIONS

PATIENT No. 25 - CAUCASIAN SKIN

RADIANT EXPOSURE (J/cm <sup>2</sup> )	REACTION AT FIVE-MINUTES	REACTION AT ONE-HOUR	REACTION AT 24 HOURS
2.6	0/5	0/5	0/5
3.7	4/5	2/5	0/5
4.8	4/5	2/5	0/5
7.1	5/5	4/5	1/5
8.8	4/4	4/4	2/4

The one-hour visible reaction in this patient was mild erythema and papule formation. (Figure 78) At 24 hours, all reactions at and below  $4.8 \text{ J/cm}^2$  had completely faded. Only a few reactions were still observable at the higher dose levels.



FIGURE 77 - PATIENT No. 25 - ONE-HOUR POST-EXPOSURE. SMALL PAPULES

ARE OBSERVABLE IN ROW 4 (7.1 J/cm<sup>2</sup>) and ROW 5 (8.8 J/cm<sup>2</sup>).

## d. DESCRIPTION OF PATIENT No. 26

The patient (R.F.) is a twenty-jour year old Caucasian male. The site of the test exposure was the flexor surface of the left forearm. The absorption data was estimated from Table I to be 42%, using the reflectance data given in Appendix A - Figure 8.

## e. DESCRIPTION OF TREATMENT - PATIENT No. 26

Five exposures were made at each of the levels of 2.3, 3.7, 4.8, and  $6.2 \text{ J/cm}^2$  for a total of 20 exposures.

Definite erythema was observed at five-minutes in most of the areas irradiated at  $3.7 \text{ J/cm}^2$  or more. No papules were observed as a result of the irradiation.

## f. RESULTS - PATIENT No. 26

Reactions are recorded as given in Table XXXVI and Figure 78.

TABLE XXXVI
Q-SWITCHED NEOLYMIUM LASER SKIN REACTIONS

PATIENT No. 26 - CAUCASIAN SKIN

RADIANT EXFOSURE	REACTION AT	REACTION AT	REACTION AT
(J/cm <sup>2</sup> )	FIVE-MINUTES	ONE-HOUR	24 HOURS
2.3	0/5	0/5	0/5
3.7	4/5	3/5	0/5
4.8	4/5	4/5	0/5
6.2	4/5	5/5	1/5

The one-hour visible reaction in this patient was a mild erythema

which faded in all but one area (dose: 6.2 J/cm<sup>2</sup>) at the 24 hour examination.

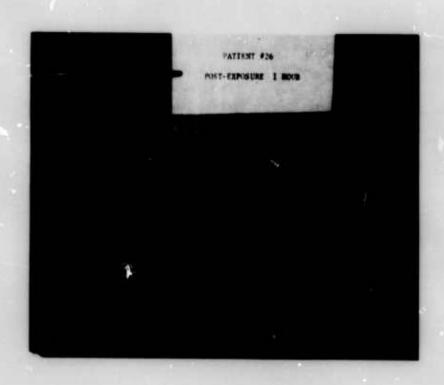


FIGURE 78 - PATIENT No. 26 - ONE-HOUR POST-EXPOSURE. A

VERY MILD ERYTHEMA IS JUST BARELY VISIBLE IN

IRRADIATED AREAS IN ROW 1 (4.8 J/cm<sup>2</sup>) AND

ROW 2 (6.2 J/cm<sup>2</sup>).

## B. Exposure Data - Negro Patients, Q-Switched Nd. Laser

PATIENTS: No. 27 (S.H.) and No. 28 (J.H.)

DATE OF TREATMENT: December 14, 1973

#### a. DESCRIPTION OF PATIENT No. 27

The patient (S.H.) is a forty-three year old Negro male. The site of the test exposure was the flexor surface of the left forearm. This patient had previously served as a volunteer for ruby laser teating (patient No. 23). During one of the exposure sessions of patient No. 16 exposures were given in a limited area (only 2 rows) on the left fore-arm. Skin reactions were recorded in both of these rows. (See Figure 32) The reactions on the patient which were observed during this session with the Q-switched neodymium laser did not occur in any area on his skin where there was any observable lesion or effect from a prior laser exposure or trauma of any other nature.

Absorption data for this patient can be estimated from Table I

Absorption data for this patient can be estimated from Table I to be 45%, using the reflectance data given in Appendix A - Figure 8.

# b. DESCRIPTION OF TREATMENT - PATIENT No. 22

Five exposures were made at each of the levels of 2.3, 2.6, and  $3.7 \text{ J/cm}^2$  for a total of 15 exposures.

The immediate reaction in the skin of this patient at a radiant exposure of  $3.7 \text{ J/cm}^2$  was an erythema with a definite white-ashen center. At the lower dose of  $2.3 \text{ J/cm}^2$ , no ashen reaction was observed, but very small papules were observed at five-minutes.

## c. RESULTS - PATIENT No. 27

Reactions are recorded as given in Table XXXVII and Figure 79.

TABLE XXXVII

## Q-SWITCHED NEODYMIUM LASER SKIN REACTIONS

PATIENT No. 27 - NEGRO SKIN

RADIANT EXPOSURE (J/cm <sup>2</sup> )	REACTION AT FIVE-MINUTES	REACTION AT ONE-HOUR	REACTION AT 24 HOURS
2.3	5/5	0/5	0/5
2.6	1/5	1/5	0/5
3.7	5/5	5/5	5/5

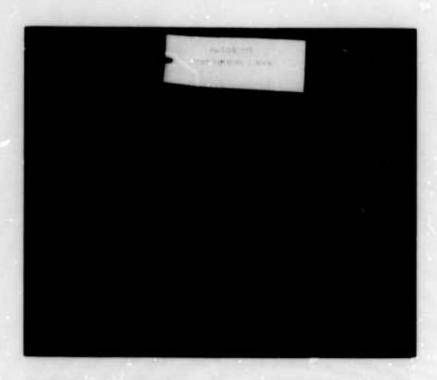


FIGURE 79 - PATIENT No. 27 - ONE-HOUR POST-EXPOSURE

NOTE DEFINITE ASHEN-WHITE LISIONS IN ROW 1

(3.7 J/cm<sup>2</sup>)

The reactions of this patient were small papules (at 2.3  $J/cm^2$  and 2.6  $J/cm^2$ ) which resided in all but one area (2.6  $J/cm^2$ ) at one-hour. The ashen-white reactions immediately observed at 3.7  $J/cm^2$  were still observable at one-hour.

A visible erythema - without the ashen center - was observable at 24 hours in all areas irradiated at  $3.7 \text{ J/cm}^2$ .

#### d. DESCRIPTION OF PATIENT No. 28

The patient (J.H.) is a thirty-eight year old Negro male. The site of the test exposure was the flexor surface of the left forearm. The absorption data for this patient was estimated from Table I to be 65%, using the reflectance data given in Appendix A - Figure 8.

#### e. DESCRIPTION OF TREATMENT - PATIENT No. 28

Five exposures were made at each of the levels of 1.8, 2.3, 2.6, and 3.1  $J/cm^2$  for a total of 20 exposures.

The immediate reaction in this patient at the level of 2.6 J/cm<sup>2</sup> was a very small ashen-white char that later (15 minutes) was in the center of a circular erythema in the areas irradiated. This ashen reaction was gone 30 minutes post-irradiation.

## f. RESULTS - PATIENT No. 28

Reactions are recorded as given in Table XXXVIII

TABLE XXXVIII

#### Q-SWITCHED NEODYMIUM LASER SKIN REACTIONS

PATIENT No. 28 - NEGRO SKIN

RADIANT EXPOSURE (J/cm <sup>2</sup> )	REACTION AT FIVE-MINUTES	REACTION AT ONE-HOUR	REACTION AT 24 HOURS
1.8	0/5	0/5	0/5
2.3	0/5	1/5	0/5
2.6	5/5	4/5	5/5
3.1	5/5	5/5	5/5

The one-hour visible reaction in the skin of this patient was a definite erythema in the areas irradiated. The ashen-white effect initially visible had disappeared at one-hour. The reaction of this patient at 24 hours was a persistant diffuse erythema in all areas irradiated at 2.6 and 3.1  $\rm J/cm^2$ . in Figure 80.



FIGURE 80 - PATIENT 28 - 24 HOURS POST-EXPOSURE. A DEFINITE ERYTHEMATOUS EFFECT IS SEEN IN ROW 1 (2.6  $J/cm^2$ ) AND ROW 2 (3.1  $J/cm^2$ )

C. Q-SWITCHED NEODYMIUM LASER - DATA ANALYSIS CAUCASIAN PATIENTS

Analysis of the data given in Tables XXXV and XXXVI for patients

No. 25 and No. 26 was done by constructing a probability curve

for each patient. This data is presented in Figure 82.

The data yielded a 50% probability for producing a minimal reaction

(MRD<sub>50</sub>) ranging from 4.2 J/cm<sup>2</sup> for mildly pigmented Caucasian skin

(patient No. 26) to 5.7 J/cm<sup>2</sup> for lightly pigmented Caucasian skin

(patient No. 25).

Direct comparison of the MRD<sub>50</sub> values to the skin absorption data was not possible due to the visible wavelength-range limitation of the device used to obtain the skin reflectance data.

As discussed in Section II-B, one can estimate from the data of Kuppenheim that Caucasian skin will absorb from 40% to 50% at the 1060 nm wavelength of the Nd-Glass laser. Thus, using reflectance of the patient's skin obtained at 700 nm as a guide, one can estimate the absorbed dose at the MRD<sub>50</sub> level as given in Table XXXIX.

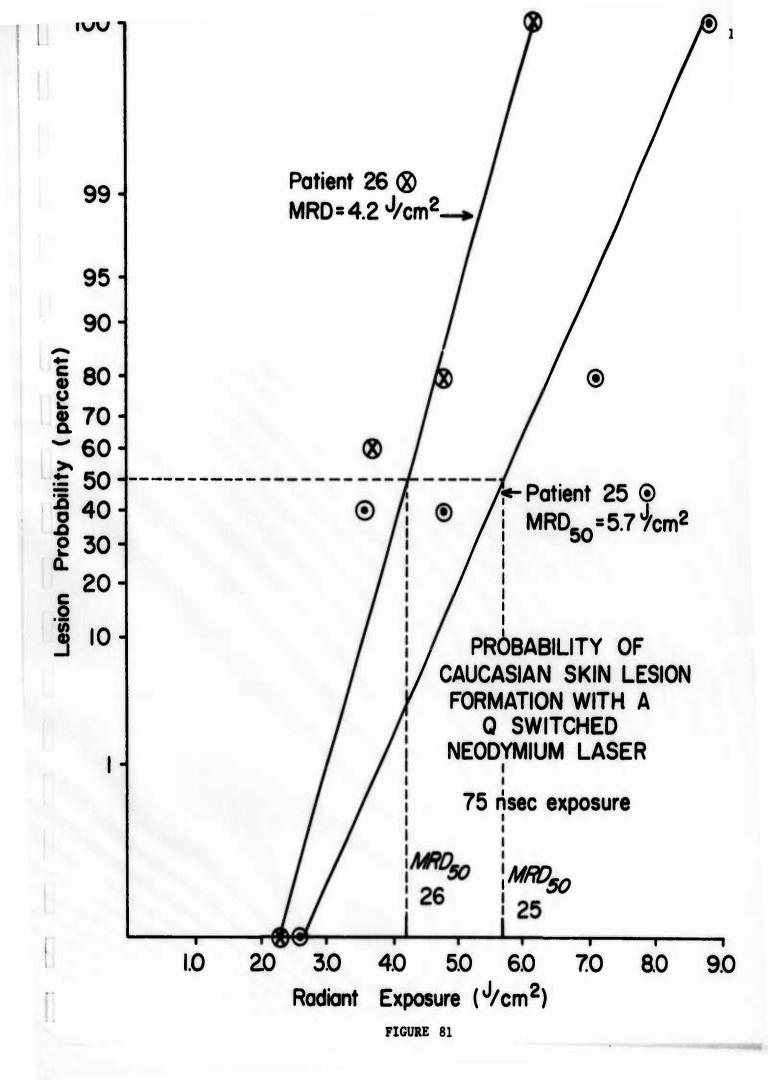
TABLE XXXIX

SUMMARY OF CAUCASIAN SKIN ABSORPTION DATA

Q-SWITCHED Nd-GLASS LASER SERIES

PATIENT NUMBER	PERCENT ABSORPTION (1060 nm)	MRD <sub>50</sub> (J/cm <sup>2</sup> )	ABSORBED DOSE (J/cm <sup>2</sup> )
25	47	5.7	2.7
26	42	4.2	1.8

\*Based on the data of Kuppenheim



Hence, it would appear that an absorbed dose of approximately  $2.2 \text{ J/cm}^2$  is the absorbed radiant exposure at which there is a 50% probability to produce a minimal reaction in Caucasian skin with the Q-switched Nd-glass laser for a 75 nsec exposure over an area of  $0.865 \text{ cm}^2$ .

D. Q-SWITCHED NEODYMIUM LASER - DATA ANALYSIS NEGRO PATIENTS

Analysis of the data given in Tables XXXVII and XXXVIII for patients

No. 27 and No. 28 was done by constructing a probability curve for each patient. This data is presented in Figure 82.

The data yielded a 50% probability for producing a minimal reaction (MRD<sub>50</sub>) of 2.9 J/cm<sup>2</sup> (patient No. 27) and 2.4 J/cm<sup>2</sup>

(patient No. 28).

Direct comparison of the MRD values to the skin absorption data was not possible due to the visible wavelength-range limitations of the device used to obtain such data. As discussed in Section II-B, one can estimate from the data of Kuppenheim that Negro skin will absorb from 45% to 65% at the 1060 nm wavelength of the Nd-glass laser. Thus, using reflectance data of the patient's skin obtained at 700 nm as a guide, one can estimate the absorbed dose at the MRD<sub>50</sub> level as given in Table XL.

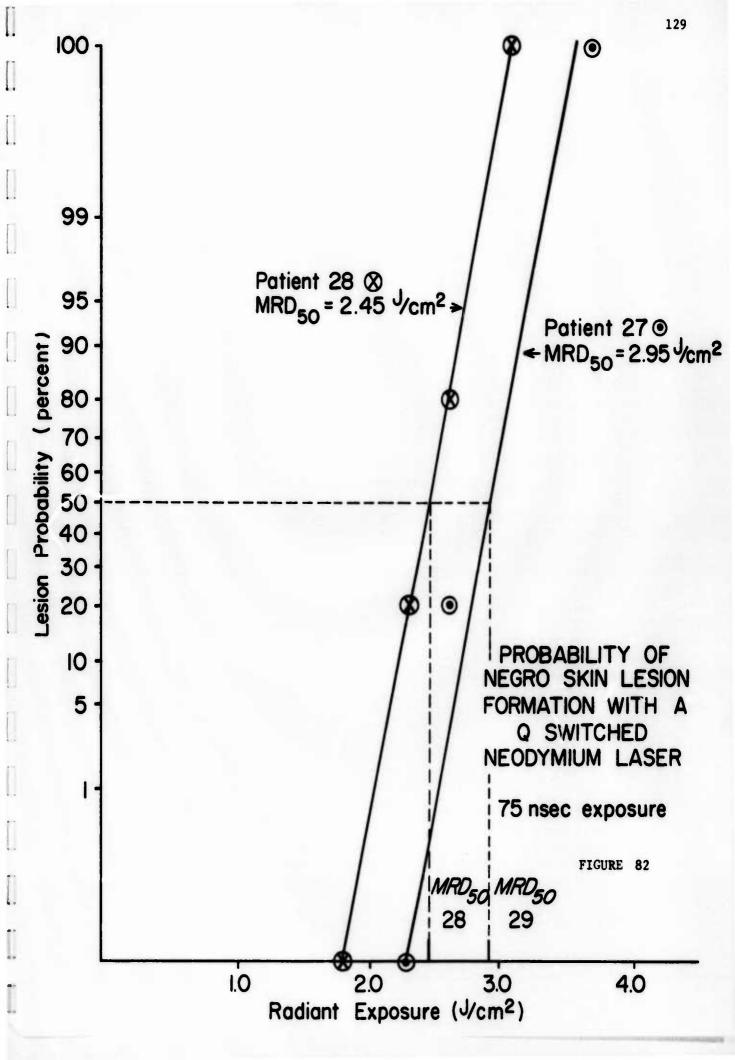


TABLE XL

SUMMARY OF NEGRO SKIN ABSORPTION DATA

Q-SWITCHED Nd-GLASS LASER SERIES

PATIENT	PERCENT ABSORPTION*	MRD 50	ABSORBED DOSE
NUMBER	(1060 nm)	$(J/cm^2)$	$(J/cm^2)$
27	45	2.95	1.3
28	65	2.45	1.6

\*Based on the data of Kuppenheim

Hence, it would appear that an absorbed dose of approximately  $1.4~\mathrm{J/cm}^2$  is the absorbed radiant exposure at which there is a 50% probability to produce a minimal reaction in Negro skin with the Q-switched Nd-Glass laser for a 75 nsec exposure over an area of  $0.865~\mathrm{cm}^2$ .

# A. COMPILATION OF EXPERIMENTAL RESULTS

1

A compilation of all the  $\ensuremath{\mathsf{MRD}}_{50}$  values for all six laser types is given in Table XLI.

TABLE XLI

	LASER	WAVE LENGTH	EXPOSURE TIME (sec)	MRD <sub>50</sub> (J/cm <sup>2</sup> )	ANSI MPE (J/cm <sup>2</sup> )
ТҮРЕ	EXPOSURE METHOD AND SKIN TYPE				
RUBY	Normal Mode Pulse  Caucasian Negro	694.3	2.5 x 10 <sup>-3</sup>	11-20 2.2-6.9	0.25
	Q-Switched Pulse Caucasian Negro	694.3	75 x 10 <sup>-9</sup>	0.25-0.34 0.25-0.30	0.02
ARGON	Shuttered Pulse Caucasian Negro	488-514	1.0	4 0-8.2 4.5-6.0	1.1
CARBON DIOXIDE	Shuttered Pulse Caucasian Negro	10,600	1.0	2.8 2.8	0.56
NEODYMIUM GLASS	Q-Switched Pulse Caucasian Negro	1,060	75 x 10 <sup>-9</sup>	4 2-5.7 2.5-3.0	0 02
YAG	Shuttered Pulse (CW)  Caucasian Negro	1.060	1.0	48-78 46-60	1.1

Included in Table XLI for comparative purposes are the maximum permissible exposure (MPE) values for skin exposure given in the American National Standards Institute (ANSI) Z-136.1 Standard on Safe Use of Lasers. (8)

Clearly, the ANSI-MPE values for skin are indeed safe levels with only nominal "safety factors" used to achieve MPE's for all laser types with the exception of the neodymium lasers operating at 1,060 nm. It would appear that the wavelength correction factor\* which is used to increase the ocular MPE's by a factor of 5 in the wavelength range from 0.7 to 1.4 nm should also be applied to the skin MPE's. As a result, the magnitude of the skin values would be increased in a manner consistant with the safety factors which were obviously employed for the other wavelength ranges.

In reviewing the data, it would appear that choice of the lowest value  ${\rm MRD}_{50}$  in any of the laser groups tested could serve to provide an equitable baseline for the purpose of establishing maximum permissable exposure limits for the types of lasers and exposure limits used. The magnitude of "safety factor" employed to convert  ${\rm MRD}_{50}$  values into Maximum Permissable Exposure levels would depend on the various risk factors of the projected laser useage

### B. EFFECTS OF SKIN PIGMENTATION

The effects of pigmentation are also clearly evident in a review of the data. Reference to Section II can yield the MRD<sub>50</sub> value for each patient as a function of the estimated or measured absorption of the skin at each laser wavelength. This data is shown in Figure 83 and is summarized below in Table XLII.

<sup>\*</sup>See page 33, Figure 7 in the ANSI-Z-136.1 Standard

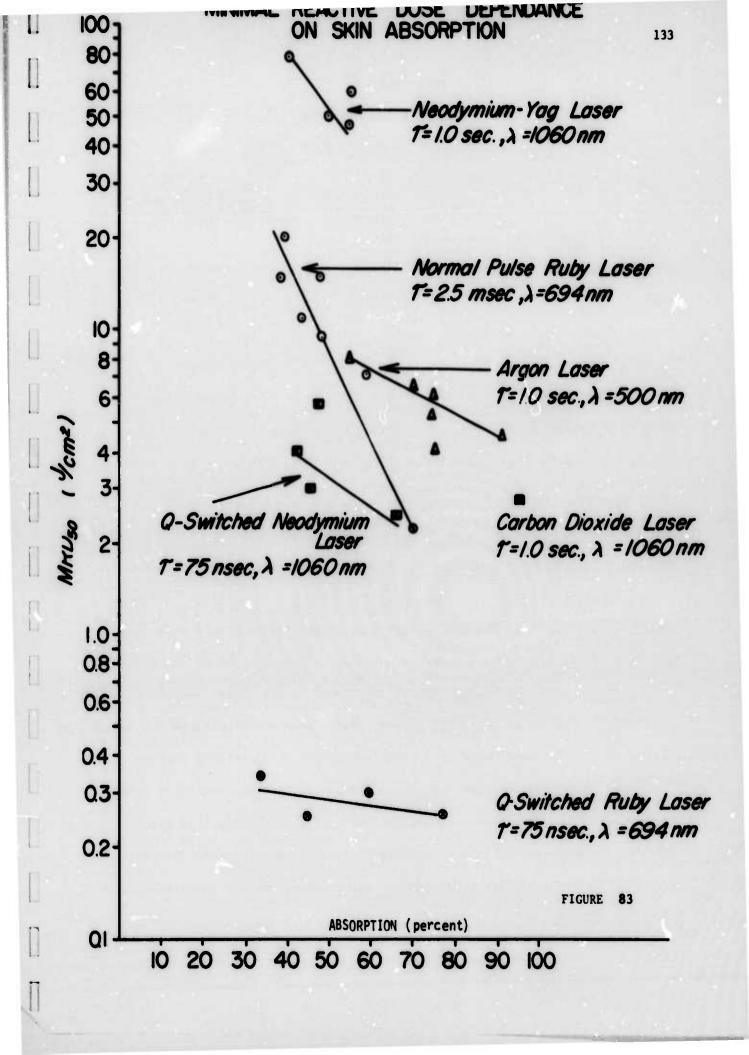


TABLE XLII

EFFECT OF ABSORPTION VARIATIONS

(SKIN COLOR) ON MRD<sub>50</sub> VALUES

LASER TYPE	WAVELENGTH	SKIN	MRD <sub>50</sub> VARIATIONS (HIGHEST VALUE MRD)	
	(nm)	ABSORPTION RANGE* (percent)		
Ruby - Normal Mode	694	38-70	9.1 times	
Argon	500	55-91	2.0 times	
Carbon Dioxide	10,600	95 (est)	1.0 times	
YAG-Neodymium	1060	40-55 (est)	1.7 times	
Ruby-Q-Switch	694	33-76	1.4 times	
Neodymium-Q-Switch	1060	42-65 (est)	2.4 times	

<sup>\*</sup>Range experienced in patients tested with laser specified.

From these results, it may be concluded that the greatest variation was observed in the normal mode ruby laser tests where a factor of ten resulted between the highest and lowest MRD<sub>50</sub> values. Hence, skin pigmentation is a rather significant factor for skin reactions with this laser type. The argon, neodymium-YAG, and both Q-switched lasers all displayed about the same variation (ranging from 1.4% to 2.4%). Hence, skin "color" is not as significant a factor with these laser types. The carbon dioxide laser yielded the same MRD<sub>50</sub> value for all patients tested. This is an anticipated result due to the constant absorption of this laser wavelength by all tissue types.

The relatively constant MRD<sub>50</sub> result obtained for the Q-switched ruby laser was not an anticipated result. As previously discussed, this can, perhaps, be explained as the coincidental result of two different "minimal reaction" criteria yielding the same value. In this case, it appears that the

ashen-white-char which is the immediate reaction in the heavily pigmented layer near the surface of Negro skin, appears to occur at nearly the same MRD<sub>50</sub> value as the erythema and papule formation which is observed at one-hour, when deeper dermal vessels of Caucasian skin are disturbed.

The ashen-white effect is not observed in Negro skin with the normal mode-ruby laser because the temperature rise required to cause this effect is not produced in the pigment layer at the lower peak-power of this laser type.

### C. ESTIMATES OF ABSORBED DOSE

The estimates of the absorbed radiant exposure dose for each laser type is given in Table XLIII.

TABLE XLIII

LASER TYPE	EXPOSURE TIME (sec)	ABSORBED DOSE (J/cm <sup>2</sup> )		
		Caucasian	Negro	
LONG PULSE RUBY	2.5 x 10 <sup>-3</sup>	4.7, 5.7, 7.2, 7.8	1.5, 4.1	
SHUTTERED CW				
co,	1.0	2.7	2.7	
YAG-Nd	1.0	24, 31	25, 33	
ARGON	1.0	3.0, 3.8, 4.5, 4.6	4.1, 4.5	
Q-SWITCHED				
RUBY	75 x 10 <sup>-9</sup>	0.11, 0.11	0.15, 0.2	
Nd-GLASS	75 x 10 <sup>-9</sup>	1.8, 2.7	1.3, 1.6	

This data has been grouped by exposure times since comparisons cannot be made between the different groups because of the  $MRD_{50}$  dependance upon exposure duration.

The results indicate that the minimal reaction produced by a long pulse ruby laser displays a strong dependance upon skin pigmentation. The higher the absorption, the lower the absorbed dose required. This would imply a shallower penetration depth, and, hence a <u>smaller volume</u> of tissue involved at the higher absorption levels.

Results with the one-second shuttered-CW pulses (CO<sub>2</sub>, YAG and argon lasers) indicate that to produce a minimal reaction occurs with the far-infrared CO<sub>2</sub> laser. The absorbed dose required for minimal reactions with the argon laser is only slightly higher and is somewhat pigment related. Exposures on skin with the Ni-YAG laser require almost ten times the absorbed dose for minimal reactions as is required by the CO<sub>2</sub> laser, implying at least ten times the tissue volume will be involved in the reaction. This depth dependance would, perhaps, explain the excessive pain associated with the Nd-YAG exposures at and below the MRD<sub>50</sub> levels.

Results of the Q-switched pulses indicate that although there is a small dependance upon skin pigmentation (about a factor of two) for both the ruby and neodymium laser types, there is a factor of ten difference in the absorbed energy required to produce a minimal skin reaction.

### D. SUMMARY

The results of this research can be concluded as follows:

 The levels of radiant exposure which produce a minimal reaction in human skin which is still observable at one-hour post-exposure were determined for six laser types. The magnitude of these MRD levels was found to depend upon:

I.

- a. Absorption of the skin at the laser frequency.
- b. Laser type (exposure duration)

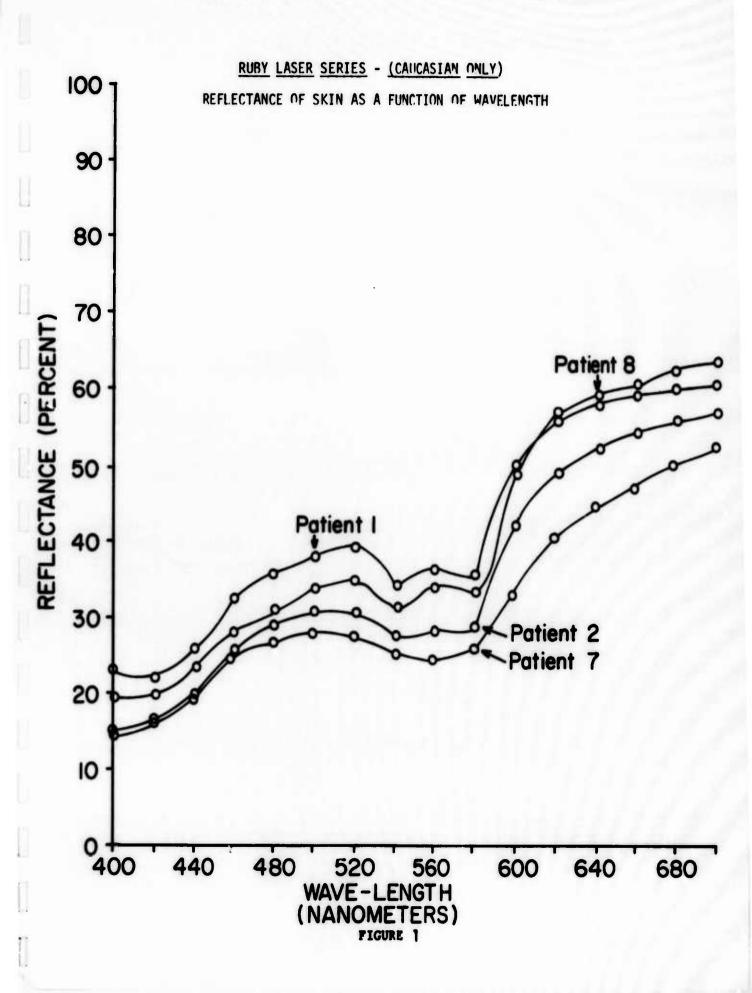
The MRD<sub>50</sub> values obtained covered a range of over three decades, ranging from as low as 0.25 to as high as  $78 \text{ J/cm}^2$  as shown in Figure 83.

Estimates of the absorbed radiant exposure dose in the skin at the  $\mbox{MRD}_{50}$  levels indicated a dependance upon exposure time and laser frequency.

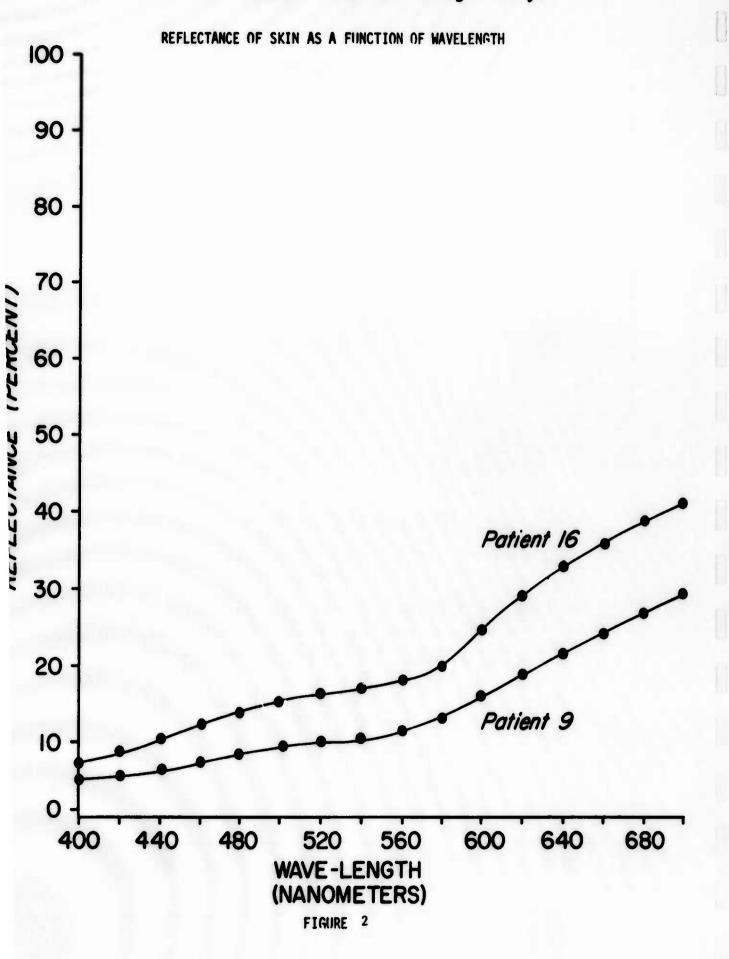
4. The 10,600 nm Carbon Dioxide yielded the lowest value MRD<sub>50</sub> (2.8 J/cm<sup>2</sup>) and was the <u>least</u> penetrating of all laser frequencies tested. The 1060 nm neodymium YAG laser yielded the highest MRD<sub>50</sub> level (78 J/cm<sup>2</sup>) and was clearly the <u>most</u> penetrating of all laser frequencies tested. The MRD<sub>50</sub> levels resulting from exposures to the pulsed 694 nm Ruby Laser displayed the greatest dependance upon skin pigmentation (absorption).

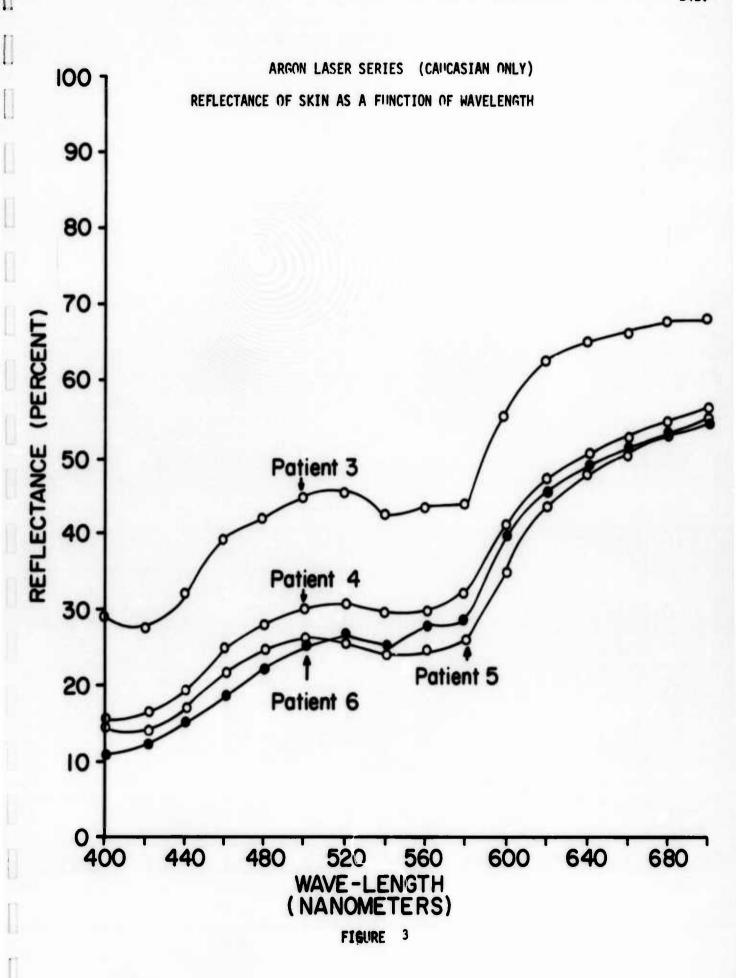
## APPENDIX A

Figure 1	Reflectance of Skin as a Function of Wavelength - Ruby Laser Series		
		Caucasian Only	.39
Figure 2	Reflectance of Skin as a Function of Wavelength - Ruby Laser Series		
		Negro Only	.40
Figure 3	Reflectance of Skin as a Function of Wavelength - Argon Laser Series		
		Caucasian Only	.41
Figure	4	Reflectance of Skin as a Function of Wavelength - Argon Laser Series	
		Series	.42
Figure 5	Reflectance of Skin as a Function of Wavelength - Carbon Dioxide Laser		
		Series	.43
Figure	6	Reflectance of Skin as a Function of Wavelength - Neodymium-YAG Laser	
		Series	.44
Figure	7	Reflectance of Skin as a Function of Wavelength - Q-Switched Ruby	
		Laser Series	.43
Figure	8	Reflectance of Skin as a Function of Wavelength - Q-Switched	1.6
		Neodymium Laser Series	.40



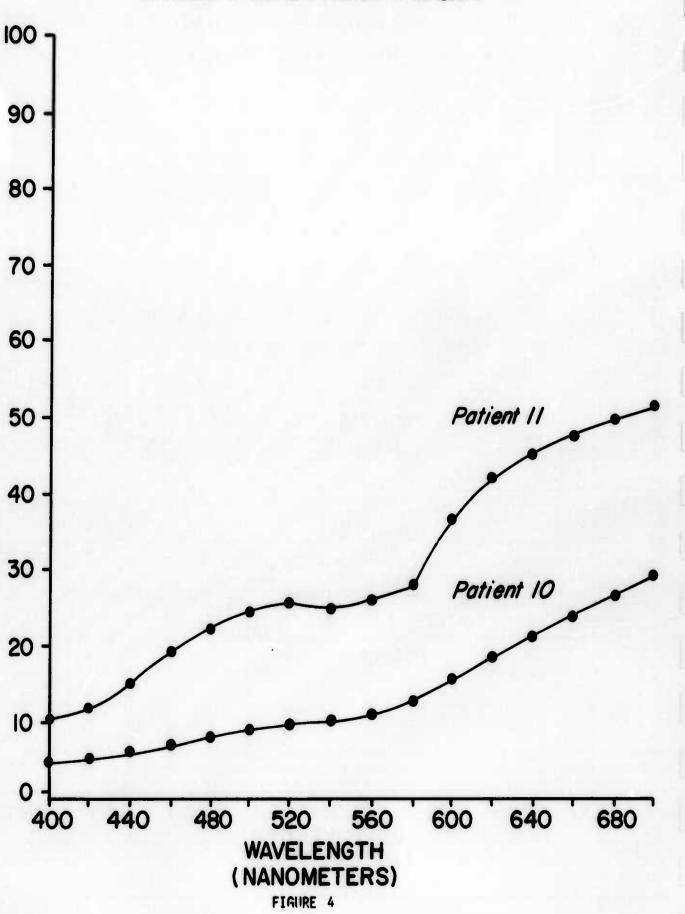
# RUBY LASER SERIES (Negro Only)





# ARGON LASER SERIES (Negro Only)

REFLECTANCE OF SKIN AS A FUNCTION OF HAVELENGTH



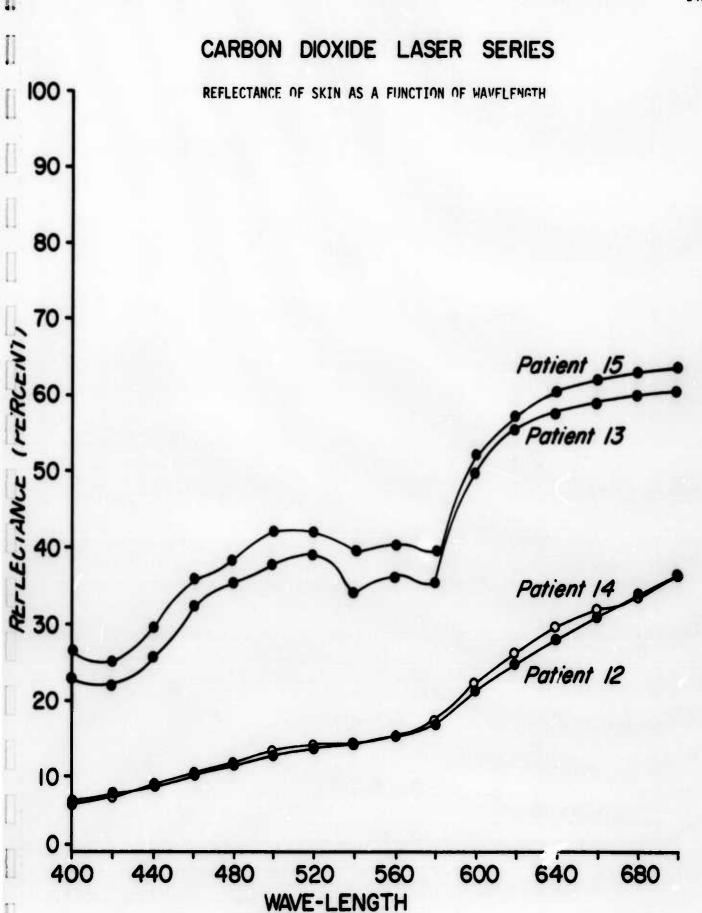
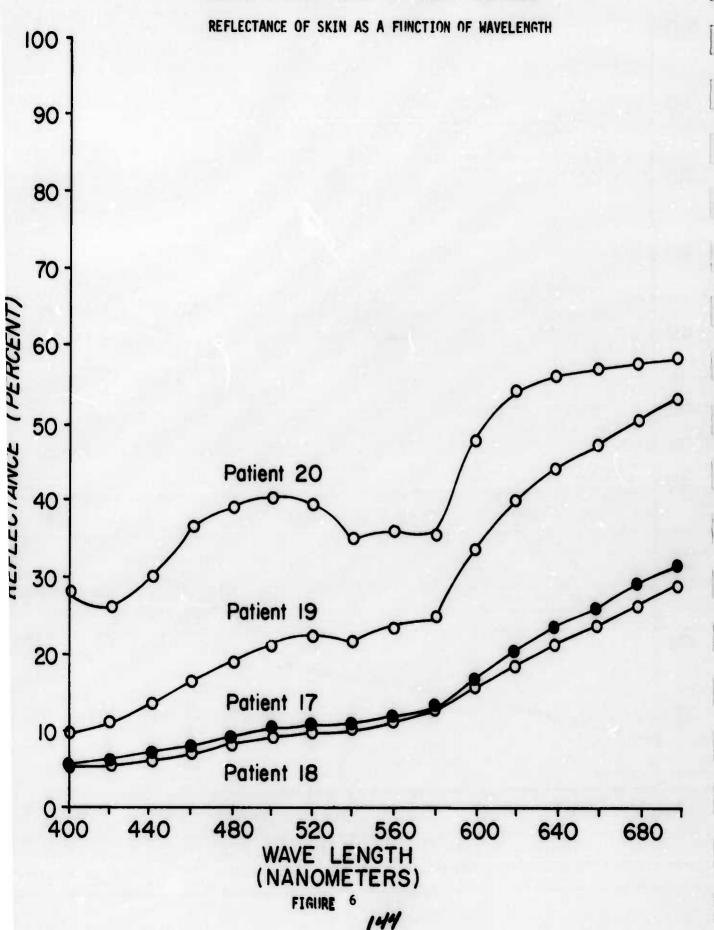
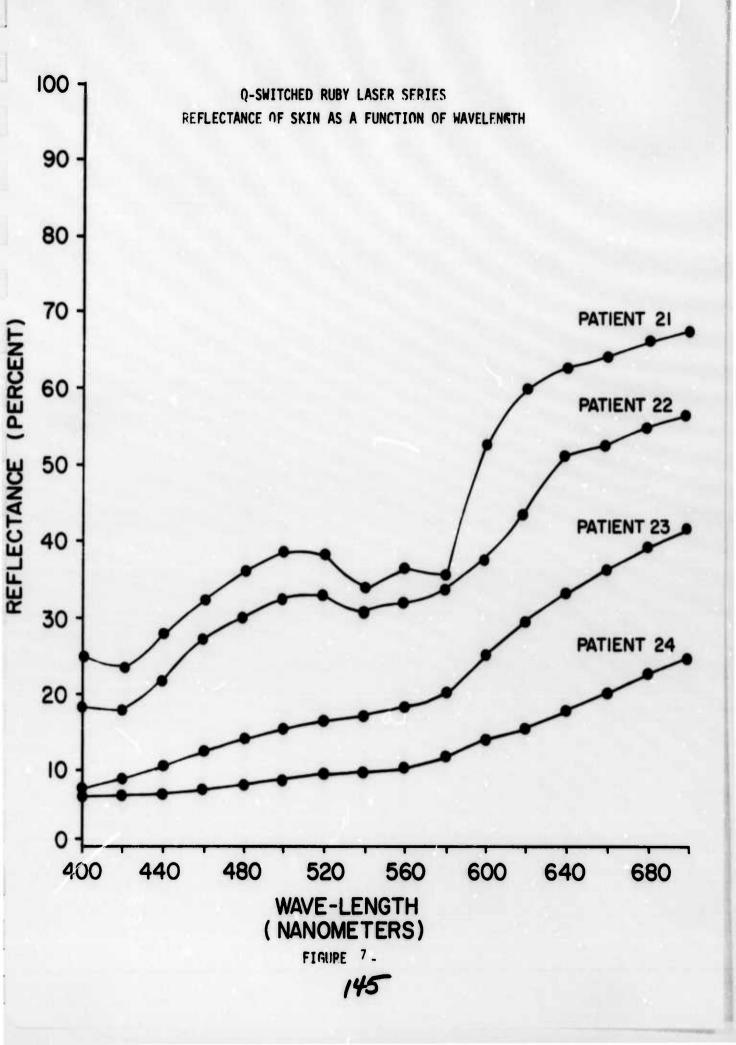


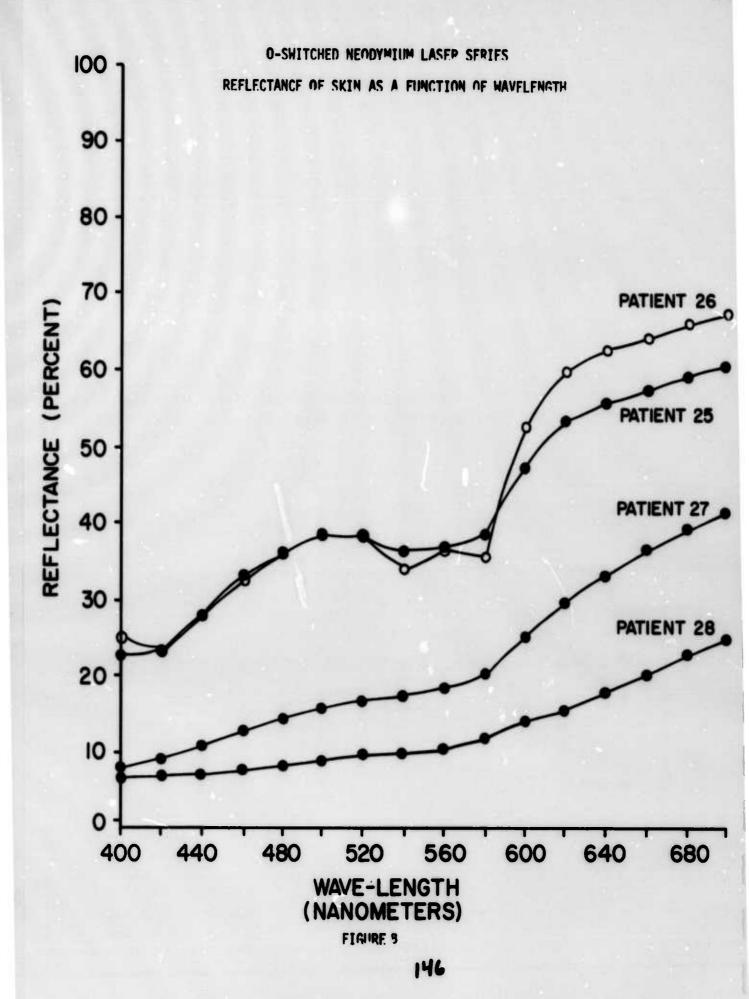
FIGURE 5

(NANOMETERS)

## NEODYMIUM - YAG LASER SERIES







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